SELF-ADJUSTING SLIDING ORTHOPAEDIC EXTERNAL FIXATOR

By

ALI ABDULLAH MOHAMMED
Reg. No. 201075241

A DISSERTATION

Submitted to

THE UNIVERSITY OF LIVERPOOL

In partial fulfilment of the requirements for the degree of:

MASTER OF PHILOSOPHY
(Orthopaedic Biology)

Department of Molecular and Clinical Cancer Medicine,
INSTITUTE OF TRANSLATIONAL MEDICINE
CANCER RESEARCH CENTRE,
200 London Road, Liverpool. L3 9TA

SEPT 2019

ABSTRACT

SELF-ADJUSTING SLIDING ORTHOPAEDIC EXTERNAL FIXATOR

By

ALI ABDULLAH MOHAMMED
Reg. No. 201075241

The aim of this work is to propose and test the implementation of a self-adjusting sliding orthopaedic external fixator that addresses the technical difficulties faced in the clinical practice in the application of the available external fixators to dislocated elbows. Applying a hinged external fixator over a dislocated elbow joint allows joint reduction and permits early joint mobilisation and rehabilitation. For a successful application of such a hinged fixator, an exact identification of the joint's centre of rotation has to be done, and it also has to be matched with the centre of the hinge. Although external fixation can be done under the general orthopaedic practice, identifying the elbow's centre of rotation is technically demanding and is usually done by a senior surgeon in a specialized centre and needs radiological imaging.

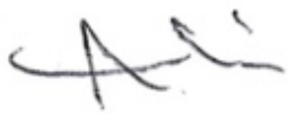
This work is a step towards easier and more feasible elbow external fixators that can be placed without radiological guidance and without the need to identify the centre of rotation.

DECLARATION

I hereby certify that this dissertation constitutes my own product, that where the language of others is set forth, quotation marks so indicate and that appropriate credit is given where I have used the language, ideas, expressions or writings of another.

I declare that the dissertation describes original work that has not previously been presented for the award of any other degree of any institution.

ALI ABDULLAH MOHAMMED



ACKNOWLEDGEMENTS

I wish to express my sincere gratitude to all of my supervisors and advisors at The University of Liverpool. Special thanks to my primary supervisor, Professor Simon P. Frostick, Professor of Orthopaedics at the Department of Molecular and Clinical Cancer Medicine, and my secondary supervisor Mr Joseph Alsousou, NIHR Academic Clinical Fellow in Trauma & Orthopaedics. Furthermore, I extend my regards and appreciation to the help and support from my advisors, Professor Paula Ghaneh and Professor Michael Schmid.

Table of Contents

LIST OF TABLES

LIST OF FIGURES

Chapter 1. Introduction

1.1 Background of the Study

Elbow fractures are relatively common in clinical practice, whereas dislocations are less common but are more devastating injuries which means they are more difficult to surgically manage whether the treatment involves open or closed techniques. This study is focused on the development of a self-adjusting sliding external fixator in the surgical treatment of elbow dislocations to replace the available hinged external fixators. This chapter gives an overview of elbow anatomy, its dislocations, common fracture patterns and the significance of external fixation in the treatment of elbow joint injuries.

When deciding to treat a dislocated elbow with external fixation, a basic spanning external fixator can be used. Spanning external fixators keep the joint stable but do not allow mobilisation and rehabilitation of the joint, whereas a hinged external fixator maintains the reduction and allows joint mobilisation and early rehabilitation.

Applying a hinged external fixator to maintain elbow joint reduction and allowing joint mobility in an attempt to prevent stiffness is a challenging combination. Modern hinged external fixators need surgical expertise to place them, specifically for identifying the centre of rotation so as to combine the two centres of rotation into one. Therefore, the elbow's centre of rotation as well as the hinge's centre of rotation need to coincide with each other for the construct of the fixator and the elbow to move as one stable unit, allowing both active and passive mobilisation.

Elbow and proximal humerus fractures account for about 4-5% of all major fractures. Most of these fractures can be treated without an operation, and the primary aim of the treatment is to achieve fracture stability and early joint mobilisation. The conflict arises between using internal or external fixation when surgical intervention is indicated (Mader, Dargel & Gausepohl 2014).

There are many classification systems available that give a better description of fracture types and complexity for academic and clinical usage. One of these classifications is Müller AO/OTA classification, which gives letters and numerical figures to different fractures at different locations. In this method, first the location of the fracture is described, followed by the type of fracture and finally the morphological characteristics of the fracture are also recorded (Müller 1990).

Bone healing is a normal process that may need our intervention to ascertain better position and function. Hence, the decision to perform surgery is only taken when it is beneficial to the patient; otherwise non-operative approaches are adopted, giving the chance to the normal biology of the fractured bone to go through its healing cascade (Bilezikian, Raisz & Rodan 2002).

Bone in the body comes in three types: woven, cortical and cancellous. Woven bone is formed during the embryonic stage and also observed during some pathological conditions and during fracture healing. Woven bony structures are later substituted by cancellous or cortical bone. While the cortical bone forms the external and internal slabs of flat bones and is present on the external shells of the long bones, the cancellous bone is located between surfaces of cortical bones. The bony scaffolding is a very dynamic structure that is under continuous yet balanced processes of formation and removal, and it is subjected to various forces and continuous remodelling. These forces aid bone formation and help shape its structure. The trabeculae of the cancellous bones are present perpendicular to the applied external forces in order to produce structural support (Bilezikian, Raisz & Rodan 2002; Miller, Thomson & Hart 2012).

Bone has osteogenic precursor cells that develop a profound layer of periosteum and endosteum. The former forms the outer surface of the bone, and the latter forms the inner medullary surface. The periosteum possesses well-perfused fibrous connective tissues that spread all over the bone except for the joint surfaces. This fibrous layer is thick and made of dense, irregular connective tissues, whereas the endosteum is composed of sheets of osteogenic cells without a fibrous component. Different bone cells are involved in the structure and homeostasis and are classified into osteoclasts, osteocytes, osteoblasts and hematopoietic rudiments of bone marrow (Kalfas 2001; Miller, Thomson & Hart 2012).

The osteoblasts are metabolically active, bone forming mature cells. When the bone forming activity ends, these cells will convert to osteocytes and lie as bone linings on the endosteal or periosteal surfaces. The osteocytes are the mature descendants of the osteoblastic cells. Those osteocytes are involved in adaptive remodelling behaviour by regulating cell-to-cell interactions with response to the local environment. The extracellular concentration of phosphorus and calcium are also regulated by the osteocytes. Osteoclasts are multinucleated and involved in bone resorption. These cells are regulated by cellular and hormonal mechanisms, and they are present in groups that are attached to the bare bone surfaces. The osteoclasts produce hydrolytic enzymes through their ruffle border. Then, those released enzymes dissolve the organic and inorganic matrices of the bone and the calcified cartilage (Miller, Thomson & Hart 2012).

Bone healing is a normal process, and our surgical intervention is aimed at achieving a proper reduction and function with open or closed techniques. For closed techniques, different types of external fixators are available. This work presents yet another technique to the function of an external fixator that can be applied to the dislocated elbow joint.

In this work the principles of the new technique are described followed by a detailed discussion of the design and further experimentation in later chapters of this work. Those experiments will deal with joint dislocations at the elbow level with ligamentous disruption. However, no fractures will be created during those experiments, as that would make testing the principles of the new sliding external fixator more challenging. If the current design concept demonstration and the experimentation were to involve a dislocated and simultaneously fractured elbow, the prototype will not only need to stabilise the dislocated elbow joint with ligamentous injuries but would also need to address the additional instability caused by the associated fractures. Clinically, elbow dislocation can present with or without associated fractures, so it is very practical and experimentally beneficial to test the concept of sliding external fixation on elbow dislocation with ligamentous disruption without associated fractures.

1.1.1 Anatomy of the Elbow Joint

The elbow is considered a complex joint, which is comprised of three articulations: the humeroradial, humeroulnar and proximal radioulnar joints. Even though it does not carry direct body weight, it can be subjected to high load bearing during sports or overhead activities. Elbow joint stability is a combined outcome of static and dynamic stabilisers, and if any of them is injured, it leads to joint instability. The passive elbow stabilisers or static constrains consist of medial and lateral collateral ligament complexes, osteoarticular anatomy and the capsule. The active elbow stabilisers or dynamic constrains are composed of the surrounding muscles (Malagelada et al. 2015).

There are two main functional movements that take place at these joints. One is flexion or extension that happens at the humeroradial and humeroulnar joints. The other movement is pronation or supination that occurs in the upper radioulnar joint in association with lower radioulnar joint. At the humeroulnar articulation, the alignment of the humerus in relation to the ulna comes at an angle that clears the forearm of the hip during gait, which is referred to as the carrying angle and measures about 12-13 degrees in males and 14-16 degrees in females, and this angle happens at the bony hinge created by the articulating trochlea and the olecranon and clinically correlating to the attitude of the forearm's long axis in relation to that of the upper arm. The humeroulnar articulation only allows the movements of flexion and extension (Kazi et al. 2017).

The humeroradial joint acts as a ball and socket joint that joins the proximal surface of the radial head and the spheroidal capitellum of the humerus. At the top position of the radial head, the radial articular facet is present, to which the capitellum articulates. The radial facet's shape is based on the capitellum's articulating part. Supination and pronation mainly happen at this articulating part of the elbow joint. The head of radius also articulates on the side with the ulna's radial notch, with the main movement at this articulation being supination and pronation as well (Fornalski, Gupta & Lee 2003).

The three joints are present inside a single lax joint capsule. The capsule is covered with muscular fibres of triceps, brachialis and anconeus muscles. There are two extracapsular epicondyles present away from the end of the humerus. All the three elbow articulations work together as one complex joint (Celli et al. 2008).

The humeroulnar articulation is the main joint that this study will refer to when discussing the elbow, as it is the place where the elbow possesses its stable hinged bony congruency that allows flexion and extension on a central axis through the trochlea and the capitellum.

1.1.2 Elbow Dislocations

In simple elbow dislocation, the process of dislocation occurs in three stages and progresses from the lateral to the medial positions depending on the severity of the injury. This type of dislocation happens due to soft tissue disruption at the lateral structures of the elbow joint, and the disruption progresses medially to affect the medial structures of the elbow joint. In the first stage the lateral structures are affected; in the second stage, the capsular structures are involved; and in the third stage, the medial structures are affected. Other associated injuries such as radial head fractures, coronoid process fractures, terrible triad injury, olecranon fracture, and Monteggia fractures also occur (Englert et al. 2013).

Open reduction associated with internal fixation by plate insertion is a well-known standard treatment for elbow fracture-dislocation. The main objectives of internal fixation are pain-free elbow movements and restoration of full function. Surgery should be performed early before stiffness sets in. Proper management of the open wounds is essential to avoid infection. Before fixation, wound type, level of wound contamination and other associated vascular injuries are also considered. In open fractures, the probability of infection is high especially when the wound is contaminated (Gupta et al. 2014).

1.1.3 Treatment with External Fixation

An external fixator is a device that aids in fracture fixation. This fixator stabilises the fractured bone with pins or wires that are connected externally to rods and clamps, which represent the body of the external fixator that stays outside the human body. Pin tracts are the skin and soft tissue penetrations created for the pins and wires to pass through. When compared to internal fixation, external fixation has major advantages such as minimal damage to the blood circulation of the involved bone, usefulness in providing stability in open fractures and reduction of disturbance to the soft tissue cover. Furthermore, with external fixation the external fixator and the fractured bone construct's rigidity can be adjusted without further surgery (Fragomen & Rozbruch 2007).

When applying an external fixator the points where the pins are applied and the regional anatomy is involved deserve special attention. Construct rigidity is affected by a number of factors such as the number of pins applied, the number of connecting rods joining the pins together and the distance intervals at which the pins are applied to the fracture site. The closer the pin is to the fracture site, the greater the pin's control in mainlining the reduction in place. Ring fixators apply pins and wires through more than one plane, which make them more stable and able to create a more rigid construct than the mono-lateral fixators that are applied through a single plane. This makes ring fixators more suitable to lower limb applications as they can bear the full body weight (Singh & Kumar 2017; Smith & Nephew 2011).

1.2 Problem Statement

In elbow dislocation with or without associated fractures, the treating surgeon may decide to manage with a hinged external fixator to stabilise the dislocation after reduction and to allow the joint to be mobilised in an attempt to prevent stiffness. The application of such a fixator needs precise identification of the joint's centre of rotation, as it represents the axis upon which flexion and extension take place.

The *Orthofix Upper Limb Galaxy System* is an available option for a hinged elbow external fixation. This system will be taken as an example to show the necessary steps to identify the centre of rotation prior to the application of the hinged external fixator. Radiological identification of the elbow's centre of rotation is surgically located by inserting a guide K-wire through the central axis of the semi-cylindrical core of the capitellum and the trochlea, which represents the centre of rotation of the humeroulnar joint where congruent flexion and extension happen. This guide wire is applied in a lateral-to-medial direction (Figure 1). While the guide wire is aiming central on the lateral view, it has to be inclined parallel to the articular surface of the distal humerus on the anterior view (Figure 2). Both the steps need multiple radiological exposures to ascertain a precise guide wire insertion. The hinged external fixator is then applied over the K-wire, so the elbow's identified centre of rotation is now matched with the centre of rotation of the hinge within the body of the external fixator. Matching the centre of rotation allows the elbow and the fixator to function as one construct (Orthofix 2019).

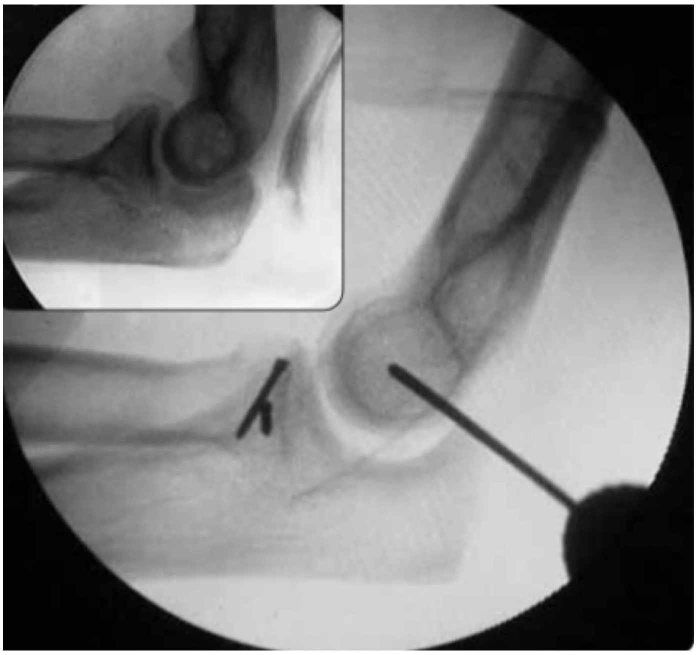


Figure 1. First step to identify the centre of rotation.

Source: Orthofix (2019)

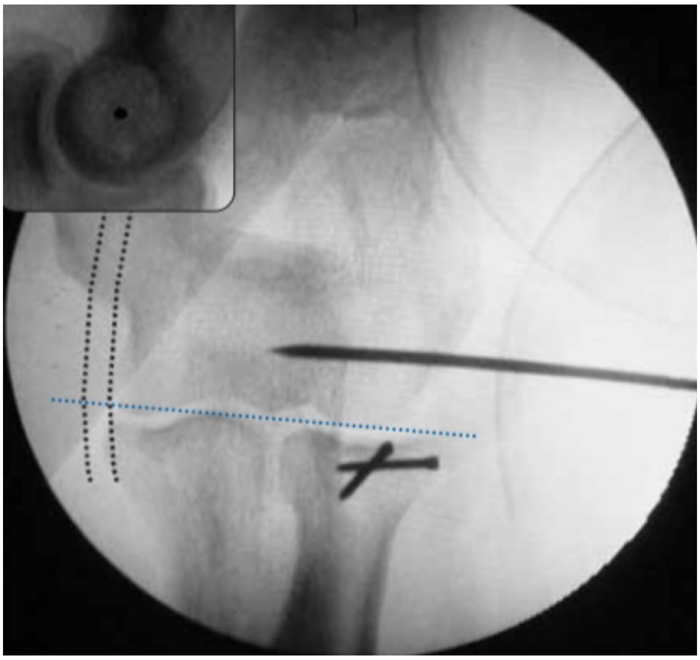


Figure 2. Second step to identify the centre of rotation.

Source: Orthofix (2019)

1.3 Aims and Objectives

1.3.1 Aims

The main aim of this study is to develop a self-adjusting sliding orthopaedic external fixator, that can be applied on the extensor surface of the elbow joint instead of the conventional laterally applied hinged external fixators. The self-adjusting external fixator can be applied through a procedure less technically demanding as the centre of rotation of the elbow joint, which need not be ascertained and matched with the centre of rotation of the hinged external fixator. Making a technically demanding procedure less complex would mean it may be carried out under the care of general orthopaedics in any district hospital, rather than in a specialized centre by a limb reconstruction surgeon specialized in external fixation.

1.3.2 Research Objectives:

The following are the major objectives of this research work:

- To design a self-adjusting sliding orthopaedic external fixator for the elbow joint.
- To patent the design's concept.
- To create a prototype that follows the design's principles.
- To be able to avoid radiological exposures during the process of external fixation, and to simplify the procedure.
- To apply the pins and the external fixator prototype dorsally, without identifying the centre of rotation, on saw-bone model.
- To repeat the experiment on cadaveric specimens.

1.4 Research Questions

The following are the research questions based on the research aims and objectives:

- How can a self-adjusting sliding mechanism in an orthopaedic external fixator be developed that can fit the elbow joint without identifying the centre of rotation?
- How can a prototype that reflects the design's concept be created?
- Would such a fixator achieve joint stability and simultaneously allow joint mobilisation?

1.5 Significance of the Study

Closed reduction and external fixation procedures are good available alternatives to open techniques, especially when dealing with open injuries with soft tissue damage. Such fixation needs related technical skills. Modifying a technically demanding surgical procedure into a simpler surgery can be beneficial in different aspects, as a simpler operation can be done earlier to avoid surgical delays and before stiffness sets in the involved joint. Additionally it would decrease the surgical time, and that can be safer for the patient. Furthermore, if the surgical procedure could become less time consuming, it would be more cost effective. Changing a major concept in external fixation design and application can propagate to other external fixation devices that may address other joints.

1.6 Limitations of the Study

The prototype used in the experiments is a handmade device, which can affect the stability of the construct. The carrying angle was not considered when making the prototype. A carrying angle of 12-14 degrees incorporated in the prototype would have made the steps of pins application and mounting the fixator on those pins easier as the fixator arms would fall in-line with the long axis of the humerus proximally and the long axis of the ulna distal to the elbow. The mismatch noticed between the long axis of the prototype and the long axis of the upper limb specimens is discussed in the cadaveric experiment.

1.7 Chapter Plan

The following is an overview of how the chapters in this study are arranged.

I. Chapter 1 is the introduction to the study and includes the study background, problem statement, aims, objectives, research questions, limitations and the chapter layout plan.

II. Chapter 2 is the literature review chapter that explores several works related to the spectrum of elbow injuries, from simple dislocations to complex fracture-dislocations, presentation patterns and management options. This chapter discusses the use of external fixation in elbow injuries, including the hinged type of external fixators that allow simultaneous stabilisation of the elbow injuries and mobilisation of the joint. Finally, this chapter shows the research gap that reflects the need for a simpler type of external fixation to address elbow injuries.

III. Chapter 3 is the research methodology chapter, which provides an overview about the research, detailed product design and prototype assembly.

IV. Chapter 4 is the experimental results and discussion chapter.

V. Chapter 5 is the conclusion and future work chapter that describes the overall research outcome obtained, conclusions, suggestions for future enhancement of the concepts based on the study findings and limitations of the study.

VI. References list, which comprises all the work of interest that has been mentioned in the text.

Chapter 2. Literature review

2.1 Introduction

This chapter provides a literature overview in relation to elbow dislocations, external fixation in general and external fixation in relation to the elbow joint. The information flow leads to the research gap, which is reflected by the need for a new external fixator design that addresses the technical issues related to the identification of the centre of rotation that affects the hinged external fixators used in current clinical practice.

2.2 Elbow Joint Injuries and Dislocations

McCabe and Savoie (2012) presented the evaluation and management of simple elbow dislocations that occur due to a fall on an outstretched hand, which leads to rotational shear forces along with axial compression across the elbow joint. These injuries are purely ligamentous. Primary non-operative treatment associated with limited immobilisation will aid in achieving early range of movement through which joint stiffness can be minimised. Extended period of immobilisation of greater than three weeks leads to poor outcome and stiffness.

Pierrart, Bégué and Mansat (2015) explored the terrible triad injuries with its management techniques. The authors described the terrible triad injury as an uncommon injury that involved posterior elbow dislocation associated with coronoid and radial head fractures. Rupture of medial and lateral collateral ligaments were also observed among the injury pattern. This type of injury carries a high risk of complications due to loss of normal alignment and the unstable nature of the associated dislocations. This could be corrected by realignment of lateral collateral ligament and fixation of the coronoid fractures. The stability of the radial head can be regained by preserving it or through prosthetic replacement. In case of persisting instability, the joint could be supported with a hinged external fixator.

Dyer and Ring (2013) studied the complications that are encountered when managing terrible triad elbow injuries. The terrible triad injury can be defined as a combination of coronoid fracture, elbow dislocation and radial head fracture. This type of injury is characterised by a persistent or recurrent dislocation, or by a joint subluxation. Proper understanding of the injury pattern and the associated fracture morphology could help in achieving the best possible management of these injuries. The major pressure and anxiety of treating a terrible triad injury is that the surgical techniques implemented for these fractures, are still difficult particularly in the realignment of the coronoid or radial head fractures and fixation.

Ring, Jupiter and Zilberfarb (2002) described the terrible triad injuries as a very difficult type of elbow injury with regard to diagnosis and management. These injuries were very unstable and prone to many complications. Computed Tomography (CT) imaging was found to aid a better diagnosis of these fractures in case of uncertainties.

Gajendran and Bishop (2014) reported a terrible triad injury associated with flexor-pronator mass and triceps avulsions due to a low-energy fall. Although terrible triad injuries could be corrected by radial head replacement or fixation, coronoid fixation and lateral collateral ligament realignment or repair, this report documented a complete circumferential injury of the elbow. The anterior capsule and the coronoid were both dislocated anteriorly, lateral collateral ligament and the radial head were dislocated laterally, the flexor-pronator mass was dislocated medially and the triceps was dislocated posteriorly. This complex injury needed reduction and stabilisation of all the dislocated structures, as the elbow was unstable until the flexor-pronator mass and triceps avulsions were repaired. The authors recommended that proper detection of any additional injuries of unusual patterns is mandatory to proceed with the required modification in the existing treatment plan.

Wells and Ablove (2008) shed light on coronoid fractures that were observed in elbow joint injuries. These fractures were considered to be rare but critical for a proper diagnosis and treatment plan. These were found to be associated with complex elbow dislocations and mainly responsible for anterior elbow instability. Proper management of minimal or large coronoid fractures is required to prevent elbow instability. The coronoid region has three soft tissue insertions, namely the brachialis muscle, anterior joint capsule and medial ulnar collateral ligament. The coronoid is crucial to elbow joint stability both for being a bony buttress and for being a point of insertion for soft tissue supporting structures. Cautious physical examination and investigation with plain radiographs were to be obtained for clear understanding of the coronoid fracture configuration. This fracture management may include soft and bony tissue repair in case of detectable elbow instability, with stiffness as a common major associated complication.

Kumar et al. (2014) presented a rare situation of anterior elbow dislocation in a young patient following a fall during a seizure episode. Compared to posterior dislocations, the anterior elbow dislocation is considered to be a very rare case of elbow joint disruption. The paper reported a 27-year-old patient with acute pain and deformity of the right elbow joint with restricted movements but no neurovascular deficit. Radiological examination illustrated non-united medical epicondyle fracture with anterior elbow dislocation. Open reduction and internal fixation (ORIF) was needed to address this injury. The report recommended early diagnosis and management for early return to normal joint function.

Kailash and Shanmuganathan (2017) reported an uncommon presentation of anterior elbow dislocation associated with neurovascular injury. The injury happened due to direct trauma to the proximal ulna during a fall on a flexed elbow. The patient had presented with elbow tenderness, pain and swelling following an accidental fall. The clinical and radiological examinations revealed anterior elbow joint disruption along with an injured brachial artery and posterior interosseous nerve; however, there was no associated fracture. Treatment procedures included instant closed reduction, repair of the primary vascular bundle and fasciotomy. The report highlighted the need of cautious neurovascular assessment in anterior elbow dislocation with a high index of suspicion.

2.3 Management of Elbow Dislocation

Ozel and Demircay (2016) reported the necessity of achieving joint stability in the management of elbow dislocations, which represent the second most common joint dislocation in the human body. Treatment of these dislocations should provide a rigid fracture fixation to gain a stable construct of a concentrically reduced elbow joint that ensures early mobilisation. Surgical procedures are the most commonly used treatment modality for the multifaceted elbow instabilities. Unstable fractured elbows are associated with several complications including stiffness, persistence of instability, heterotopic calcification, myositis ossifications and neurovascular dysfunctions. Success of treatment is primarily based on the proper recognition of the injury pattern and restoration of joint stability.

Kanakaraddi (2013) reported the use of total elbow replacement for the treatment of an old unreduced complex elbow dislocation. A 65 years old patient had originally presented with elbow dislocation after a fall on an outstretched hand. Two months later, the patient was found to have fixed flexion deformity (50 degrees) with a range of movement of 50-60 degrees. The patient was treated surgically by performing a total elbow joint replacement using hinged elbow prosthesis. After six weeks the patient showed a good improvement in elbow functions and was able to carry out daily routines.

Kim et al. (2011) explored the complications associated with total elbow replacement for elbow dislocations. Though modified design and improvised techniques resulted in increased use of total elbow joint replacement surgery, complications have also increased resulting in non-salvageable disabilities. The complications due to total elbow replacement surgery included fractures around the implant, infection, implant loosening, nerve palsy, and triceps insufficiency. The number of total elbow replacement performed was comparatively low, but the proportion of complications was high.

Kamrani, Farhadi and Zanjani (2015) reported the advantage of using external fixator in association with ORIF in elbow dislocations. Twelve patients presented with old untreated elbow dislocations that were subsequently managed with open reduction and fracture fixation with reconstruction of the associated soft tissue injuries. Besides bony and soft tissue reconstruction these elbows were supported with hinged external fixation to enhance the range of movement rehabilitation and to achieve faster joint mobilisation. Based on Mayo's elbow score, it was found that these patients showed good clinical outcome. Thus, the researcher recommended the use of external elbow fixation in achieving early range of motion while maintaining the concentric reduction.

Ouyang et al. (2013) expounded the advantages of using external fixation even after internal fixation. Elbow stiffness is considered to be the most predominant problem associated with elbow dislocations. Although open reduction and internal fixation served as one of the approved techniques of elbow architectural repair, the stiff elbow with non-union distal humerus could be suitably treated with additional external fixation. The use of unilateral external fixation to supplement open reduction and internal fixation was found to be effective, reliable and well tolerated by patients.

Elbow external fixation is better suited for acute instability, chronic instability, terrible triad injuries and fracture-dislocations as well as for providing an extended healing period for the associated ligamentous injuries (Panchal & Murthi 2012). These fixators help in maintaining a congruent and stable elbow joint. Additionally they also allow healing of acute or chronic soft tissue injuries, while allowing joint mobilisation with the aid of hinged fixators that have been well centred to match the joint's centre of rotation (Chen & Julka 2010).

2.4 Review of Existing Fixators for Elbow Dislocations

2.4.1 Hinged External Fixators

Poglia et al. (2016) reported radial nerve palsy after using hinged external fixation for a complex elbow fracture-dislocation. A 39-year-old patient was managed with hinged (adjuvant) external fixator for a terrible triad elbow injury. After seven weeks, an injury of the radial nerve was confirmed at two levels opposite to the humeral pins. The pins were removed cautiously and partial nerve grafts were performed. This report concluded that hinged external fixators are needed in treating complex elbow fracture-dislocation, but they can be associated with the risk of radial nerve injury.

Sakai et al. (2016) presented 11 patients (8 with terrible triad injuries and 3 with olecranon fracture-dislocation) of complex elbow dislocations treated with primary hinged external fixator during the period from June 2012 to December 2014. Ten patients were supported with radial head replacement (RHR), and olecranon fixation was performed in three patients. No patient was treated for collateral ligament injury and displacement of coronoid fractures. After surgery the patients were evaluated with a 16-month follow-up period. Results revealed that the Elbow Performance Score was found to be 93. Out of the 11 patients, 5 had a good result and 6 had an excellent result. One patient required bone grafting after the initial procedure.

Hopf et al. (2015) reported the subjective and objective outcomes of treating unstable elbow dislocations through hinged external fixators. The report revealed the results of 26 patients using the Mayo performance score as a quantitative parameter for outcome assessment. Eight patients showed a mild residual instability, but the majority had an excellent outcome.

Bigazzi et al. (2015) explored the implementation of a new auto-centric laterally applied hinged external fixator that could be fixed without an articular pin. The self-aligning capacity of the fixator enables it to align itself according to the elbow range of movement. Seven patients with post-traumatic elbow fracture-dislocation were treated with this auto-centric external fixator. Construct alignment and position were assessed based on CT scans and radiographs. No cases were reported for loss of fixation, misalignment, instability or pin loosening. The surgical procedure was also comparatively easy and quick to learn. The authors concluded that this new fixator is functional and does not obstruct distal plate and screws fixation or ligamentous reconstruction anchors.

Wang et al. (2014) suggested the use of hinged external fixators in the treatment of severely stiff post-traumatic and non-mobile elbows. The report reviewed 46 patients with post- traumatic stiff elbows. Suture anchors were used for ligamentous restoration, and hinged external fixators were required to protect the vulnerable ligaments and to facilitate rehabilitation. A follow-up of 24.3 months revealed that the Mayo score was 91, which is an improvement from the score of 63 prior to surgery. A moderate instability was reported in some patients on removal of external fixator, and ulnar nerve palsy was observed in seven patients. Three patients already had ulnar nerve palsy preoperatively.

Maniscalco et al. (2014) reported the treatment outcomes using a new articulated hinged external fixator for complex elbow dislocations in a group of elderly patients. The process is less invasive when compared with internal fixation. Nineteen patients were treated with this external fixator for complex elbow fractures. The treatment outcomes were assessed based on factors such as pain, function, joint's movement, reoperation rate and type of complications. The results of this study showed the use of hinged external fixators as a better substitute to ORIF, total elbow replacements and conservative treatment options.

Potini et al. (2015) described the complications associated with the treatment of chronic elbow dislocations with hinged external fixators. Seven cases with chronic elbow fractured-dislocations were treated with internal fixation first, followed by hinged external fixation. After a follow-up period of 8 months, a significant improvement in the elbow range of movement was observed. This study reported a high complication rate; complications ranged from pin site infections, fracture through pin site, and even osteomyelitis.

Schep et al. (2011) presented a work on the treatment of complex elbow dislocations with a combination of ORIF and hinged external fixation. A set of 30 patients who presented with complex elbow dislocations were supported with hinged external fixators due to residual instability. Those patients were treated with early motion exercises immediately after surgery within the pain limits. A clinical outcome follow-up of 12 months was performed, which showed improvement in the range of movement and reduction in joint stiffness.

Yu et al. (2015) investigated the functional outcome of hinged external fixators in the treatment of delayed mal-union or non-union of fractured capitellum with a mean of 3.7 months delay from initial trauma. The study was conducted during February 2007 to February 2012. Patients were treated with ORIF and supported by hinged external fixation. A mean follow-up of 28 months revealed improvement in the flexion arc. The Mayo score ranged from 56 to 93. No cases with secondary displacements were identified.

Zilkens et al. (2009) undertook a retrospective investigation of the radiological and clinical outcome in post-traumatic chronic or acute elbow instability. The study reported the outcome of 24 patients treated with ORIF and supported with hinged external fixation. Eleven patients suffered from acute instability due to dislocation, and the rest had chronic elbow instability. The treatment allowed early intensive mobilisation in addition to sufficient range of motion and concentric stability.

Iordens et al. (2015) expounded on the functional outcomes in the treatment of complex elbow dislocations through hinged external fixators. The study was conducted among

27 patients for about 2 years with a follow-up at 3, 6 and 12 months after the operation. The functional outcomes were evaluated with the disabilities of the arm, shoulder and hand (DASH) score, Mayo score and Mayo performance index (MEPI), range of motion and radiographic analysis. The treatment enhanced the mobility of the treated elbows with less complications compared to other conventional treatment options.

2.4.2 Circular External Fixators

Chida et al. (2016) proposed treating comminuted distal humeral dislocations with Ilizarov technique, by using ring fixation in those patients who presented with osteoporosis and rheumatoid arthritis to achieve better bone union and extended elbow function. The elbow of a 58 years old woman was supported with an Ilizarov ring fixator for the treatment of a comminuted distal humeral fracture-dislocation and was continuously evaluated for functional outcomes for about 18 months. This technique was reported as comparatively less invasive compared to open surgery and ensured earlier rehabilitation and better bone stabilisation.

Bari et al. (2015) reported the treatment of neglected elbow dislocation with Ilizarov ring fixation technique. Fourteen patients (2 females and 12 males) were treated with ring external fixators with medial or lateral or even combined approaches. Mild cases were treated only with the lateral approach. Ring fixation was considerably better and less invasive when compared to open procedures.

Burg et al. (2011) presented a report on the functional outcome of distal humerus elbow fractures that were treated with external fixation technique using non-bridging ring fixators. The study was carried out on 10 patients aged between 70 and 89 years, of whom three had type A supracondylar fractures and seven had type C intercondylar fractures. After surgery, patients were subjected to immediate post-operative mobilisation of the elbow joint. The fixators were placed for about 62 to 90 days. The average time taken for bone union was 56 days. Patients showed good restoration of functional joint movements. Complications like transient radial nerve palsy and superficial decubitus ulcer were observed in two patients. Ring fixators have permitted immediate mobilisation, which makes them a good surgical tool to use before considering elbow replacement surgery or even internal fixation.

Safoury and Atteya (2011) studied the treatment of non-union supracondylar humeral fracture-dislocations by implementing Ilizarov ring fixation method. The study included eight patients with a mean age of 45.73 years. Follow-up was over a period of three years during which the patients were evaluated by the DASH score. Solid bony union was achieved in all eight patients. No pain and no occurrence of infections were observed. All the patients were speedily rehabilitated and achieved good functional outcome. The treatment is reported to be effective, well tolerated and reliable.

2.4.3 Joshi's External Stabilisation System (JESS)-Type Fixators

Saha, Ray and Behara (2016) studied the use of Joshi's external stabilisation system (JESS) fixator type for the treatment of comminuted distal humeral fracture-dislocations. A group of 75 patients (40 females and 35 males), over 60 years old were studied. The fractures were reduced and fixed with K-wires prior to the application of JESS fixator. The follow-up period was over 1 year, and clinical outcome was evaluated based on the Mayo score. Several complications including osteomyelitis (7 patients), radial nerve palsy (3 patients) and pin tract infection (15 patients) were observed. Furthermore, the achieved range of movement was excellent in 40 patients and good in 35 patients.

Ghosh et al. (2015) reported the usage of JESS fixators for the management of supracondylar humeral fractures in adults. Thirty patients of whom 18 had open fractures and 12 had closed fractures were included. Based on the AO classification, 16 had C1 fractures and 14 had C2 fractures. All the patients were treated with JESS fixators and followed up for a period of 10 months. The functional evaluation of the treatment was based on Cassebaum's functional system. In closed fractures about 67% of the patients were found to have excellent results, and 33% had moderate results. Among the 18 patients with open fractures, 33% showed excellent results, whereas 67% had a poor outcome.

Table 1. Existing types of fixators with their advantages and disadvantages.

Type of fixator	Author	Year	Implicated for	Advantages	Disadvantages
Hinged Fixator	Poglia et al.	2016	Terrible triad Injuries	Applicable for complex fractures	Radial nerve palsy
	Sakai et al.	2016	Terrible triad injuries and olecranon fracture-dislocations	Minimally invasive procedure, early mobilisation and no elbow instability	
	Hopf et al.	2015	Unstable elbow dislocations	Excellent closed reduction	Residual instability
	Wang et al.	2014	Severely stiff elbows and non-mobile elbows	Restoring functional mobility in case of stiffed elbows	Residual instability and ulnar nerve palsy

Type of fixator	Author	Year	Implicated for	Advantages	Disadvantages
	Maniscalco et al.	2014	Complex elbow dislocations	Better tolerance and low pin track infections	
	Potini et al.	2015	Chronic elbow fractured dislocations	Better mobilisation	Higher risk of complications, possible treatment failure and additional procedures
	Iordens et al.	2015	Complex elbow dislocations	Improved stability and early mobilisation	
	Zilkens et al.	2009	Acute and chronic post-traumatic elbow instability	Early intensive mobilisation and significant range of movement	
	Schep et al.	2011	Complex elbow dislocations	Better range of motion and reduced elbow stiffness	
	Yu et al.	2015	Elbow stiffness along with non-union or mal union of capitellum fracture	Reduces stiff elbows arising due to delayed diagnosis of capitellum fracture	
	Bigazzi et al.	2015	Simple elbow dislocations	Auto-centric and promotes early post-operative mobilisation	

Type of fixator	Author	Year	Implicated for	Advantages	Disadvantages
Circular / Ring (Ilizarov technique)	Chida et al.	2016	Comminuted distal humeral fracture-dislocation	Better union, and early mobilisation	
	Bari et al.	2015	Neglected elbow dislocation	Early mobilisation, effective and reliable	
	Burg et al.	2011	Distal humeral dislocations in the elderly	Minimal invasion, immediate mobilisation	Transient radial nerve palsy and superficial ulceration
	Safoury & Atteya	2011	Non-union supracondylar humeral fracture-dislocation	No pain, complete soft tissue recovery	
(Joshi's External Stabilisation System) JESS-type Fixators	Saha, Ray & Behara	2016	Comminuted distal humeral fracture-dislocation	Applicable for open and closed fractures with better range of movement	Osteomyelitis, iatrogenic radial nerve palsy and pin tract infection
	Ghosh et al.	2015	Supracondylar humeral fracture	Applicable for open and closed fractures	

Source: Author's own

2.5 Research Gap

The implementation of external fixators for the treatment of elbow dislocation is now gaining more importance as the technique is less invasive when compared to open reduction and internal fixation (Gupta et al. 2014). The hinged external fixators are best suited for terrible triad injuries (Sakai et al. 2016), complex and unstable elbow dislocations (Ferenac, Hart & Kozak 2013; Iordens et al. 2015; Maniscalco et al. 2014; Schep et al. 2011), severely stiff elbows (Yu et al. 2015) but they are also associated with several complications including radial and ulnar nerve palsies, residual instability (Poglia et al. 2016; Wang et al. 2014), and pin site infections (Potini et al. 2015). The circular fixators or Ilizarov ring fixation technique can be used in treating comminuted distal humeral fracture-dislocation (Chida et al. 2016), olecranon fracture-dislocations (Nemade et al. 2015), neglected elbow dislocations (Bari et al. 2015) and for non-unions of supracondylar humeral fracture-dislocations (Safoury & Atteya 2011). However, complications such as transient radial palsy and superficial decubitus ulcer (Burg et al. 2011) are possible when using Ilizarov technique. Joshi's External Stabilisation System or JESS fixators are cost effective and less invasive (Ghosh et al. 2015) but are susceptible to osteomyelitis, iatrogenic radial nerve palsy and pin tract infections (Saha, Ray & Behara 2016). Applying an external fixator on the extensor surface of the elbow joint, while using a self-adjusting sliding type of external fixator in the treatment of elbow dislocation, has not been explored and studied so far. Hence, this thesis works on the concept of a self-adjusting sliding external fixator patented design (UK Patent Number: GB2519981). This work will demonstrate the design's concept and experimental testing in dealing with elbow dislocations to provide a stable joint that can still be mobilised to prevent stiffness (Mohammed & Frostick 2015).

Chapter 3. Research Methodology

3.1 Introduction

This chapter presents a detailed description of the self-adjusting sliding orthopaedic external fixator's patented product design (UK Patent Number: GB2519981), detailed components and function. Additionally it discusses the research approach, research design, prototype assembly and experimental testing (Mohammed & Frostick 2015).

3.2 Research Approach

Research approaches are the plans and procedures for research that span the steps from broad assumptions to detailed methods of data collection, analysis and interpretation. The overall decision involves which approach should be used to study a topic. Research approach can be quantitative, qualitative or a combination of both (Creswell 2014).

External fixation is an admirable substitute to open surgery for treatment in high-risk patients presenting with fractures, and it provides a low-risk operation with quicker mobilisation, minimal blood loss, decreased cost, and few post-operative complications due to the short period of hospitalization (Monreal 2016).

This research will be employing external fixation in dealing with elbow dislocation, with no internal fixation and with no ligamentous repair. The research approach followed in this study is qualitative.

3.3 Product Design of the Sliding External Fixator

3.3.1 Principles and Description

The principle of this design is to provide an external fixator that can be applied on the extensor surface of the elbow joint in a simpler way than the currently available lateral application techniques. This new design does not need any radiological guidance to identify the elbow's centre of rotation. This sliding fixator aims to achieve a congruent elbow joint specifically at the articulation between the distal humerus and proximal ulna, as it is the main articulation with the anatomical bony congruency. The fixator would keep the joint reduced and at the same time permit passive, passive assisted or active mobilisation of the joint.

The design consists of two frame members (first and second), with a square cross-sectional area hinged together behind the elbow and two rods with a square cross-sectional area. Each rod member is meant to slide in and out its corresponding frame member. The bases are components that clamp the free non-threaded ends of the pins, which on the other threaded ends, are inserted in predrilled holes in the bone (the ulna and the humerus). Those bases are attached to the rods, so both the bases and the rods move as one unit; if the pins are clamped directly to the rods, no separate bases are needed.

A recoiling mechanism is fixed to both rods and to the hinge (at those ends which are closer to the elbow). The rods are kept in the frames in such a way that the rods slide out of their corresponding frames during elbow flexion, while the recoiling mechanism keeps them partly within the frames in flexion and hence prevents disengagement. The same recoiling mechanism helps the rods slide back in the frames during extension.

Therefore, the components of each limb of the fixator on either side of the hinge slide to lengthen that fixator's limb in flexion and the opposite happens in extension.

3.3.2 Sliding Fixator Application and Function

When this fixator is applied to the elbow, the pins are fixed to the humerus and the ulna from posterior to anterior, and the free end of the pins are then fixed to the bases. The hinge is kept behind the elbow in line with the subcutaneous border of the ulna at the level of the elbow joint, without any radiological attempt to identify the centre of rotation. The radiological identification of the joint's centre of rotation used in the conventional hinged elbow external fixators is omitted in this design, and this step is overcome by the sliding mechanism of a posteriorly applied sliding fixator, in such a way that the length of the two limbs of the fixator (proximal and distal to the hinge) get adjusted spontaneously during joint movement.

Irrespective of the type of the recoiling mechanism that is implemented in the design, it has to be in tension to hold the rods in the frames. This tension is more in flexion than in extension, but it is never less than the weight of the forearm in standing position so that it is stable and does not disengage from the fixator. The rods should fit snug within their frame members, to allow sliding as well as provide rotational stability by preventing rotational movements if a longitudinal torque is applied on the long axis of the construct.

The design presented here used a model of bars and frames with a square cross-sectional area, but other geometrical matching shapes can be used, such as pentagonal for example, as the more precise the conformity between the bars and the frames, the more likely they would provide additional rotational stability of the whole construct.

However, the geometrical conformity should not be too complex as that might jam the sliding mechanism, which would defeat the whole purpose of the application. The rods can have bases fixed to them, or the rods themselves designed with built-in holes or even clamps to accommodate a locking place for the free edge of the pins. In this model the frames extend over the corners of the bars, while keeping slotted space for the pins, so the pins do not interrupt the sliding mechanism.

3.3.3 Diagrammatic Representation of the Sliding External Fixator Design’s Components and Function

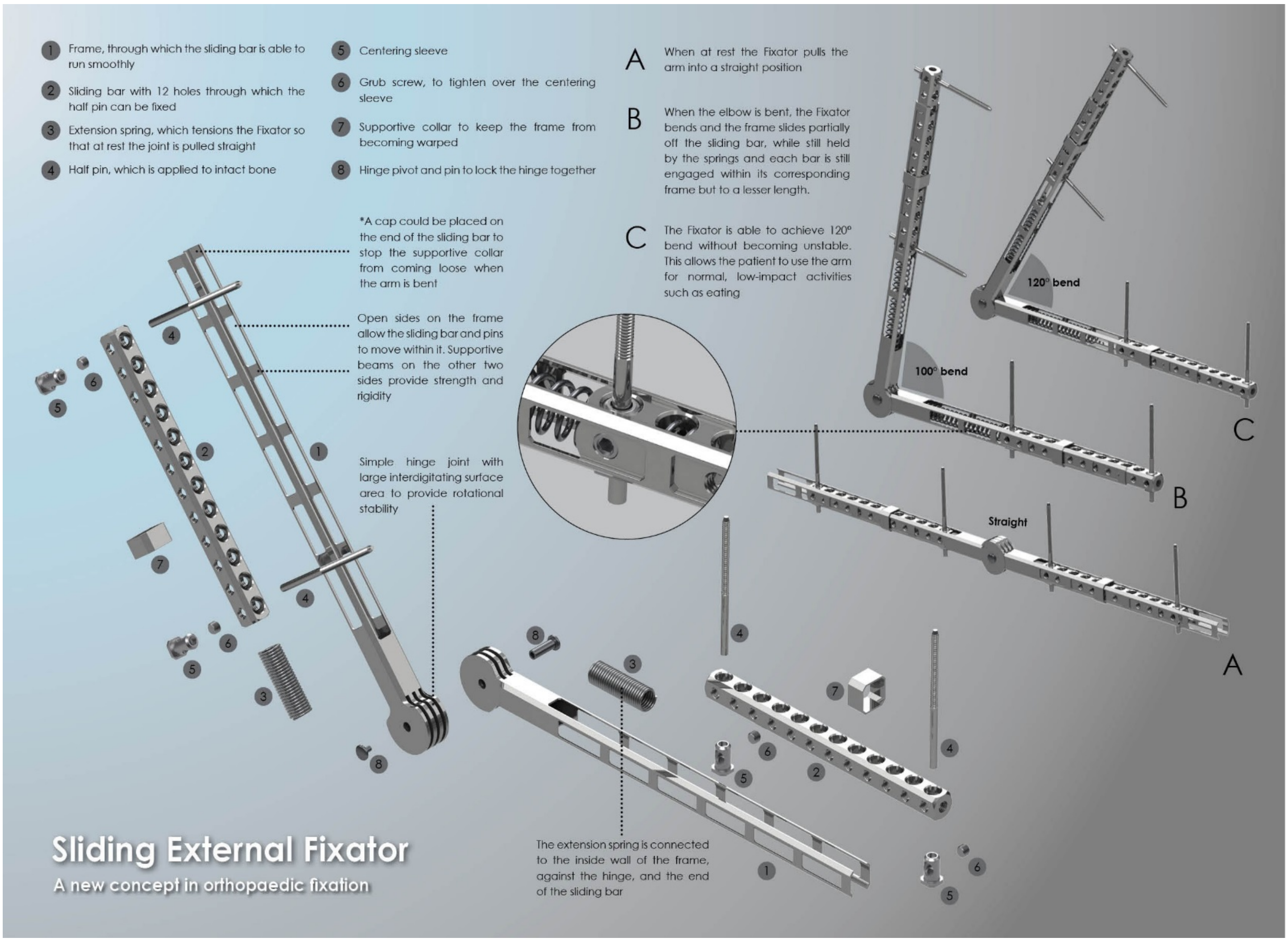


Figure 3. The different components of the sliding external fixator.

Source: Mohammed (2018)

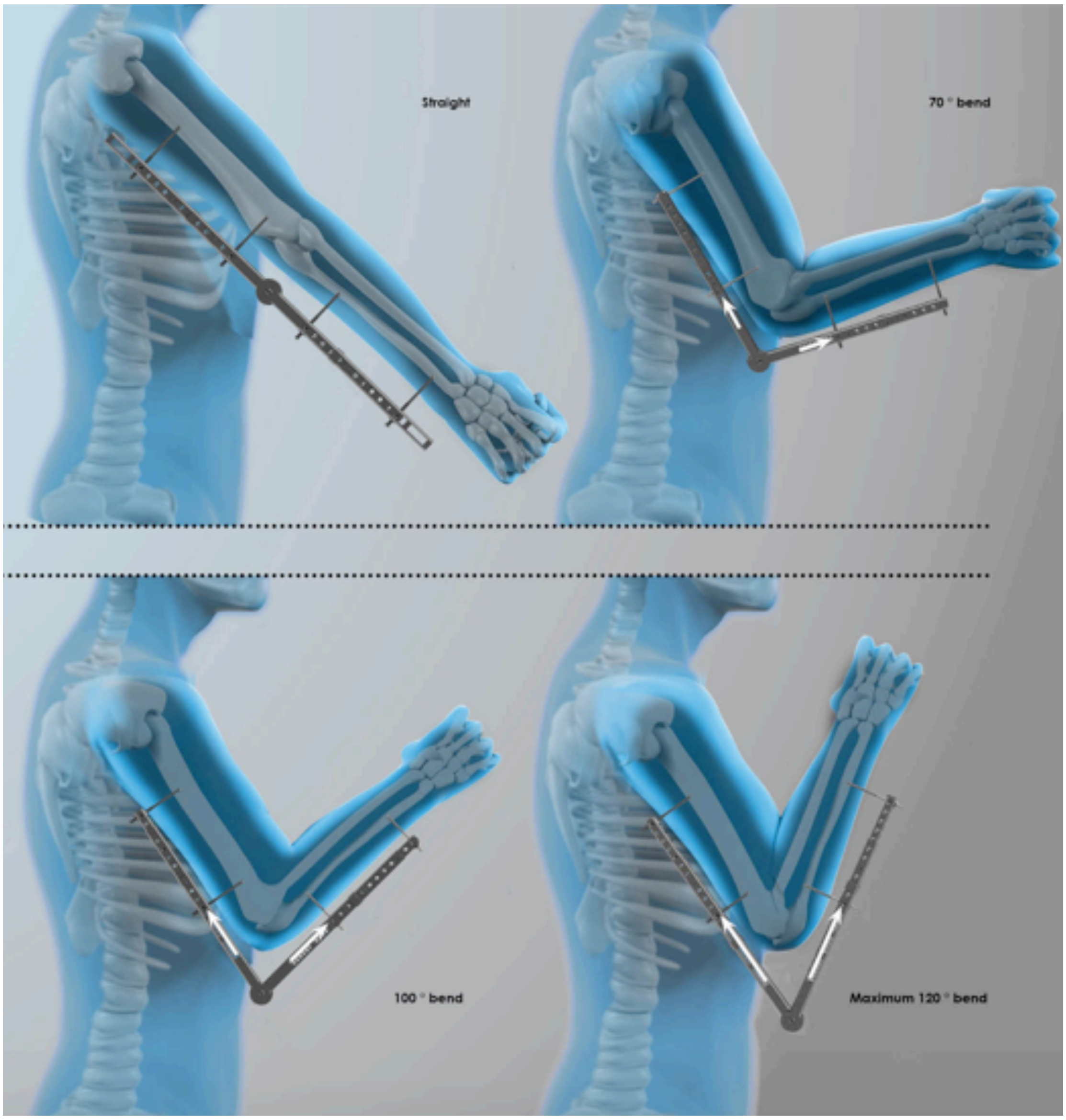


Figure 4. The sliding external fixator in action.

Source: Mohammed (2018)

3.3.4 Detailed Description of the Sliding External Fixator's Design (UK Patent Number: GB2519981)

Figure 3 shows the frames through which the sliding bars would fit snugly and slide during use. Each bar or frame has a central end that is close to the elbow and a peripheral end which is away from the elbow. The central ends of the frames are connected directly to a hinge, while the central ends of the bars are connected to a spring, which is then connected to the hinge.

A typical Rancho cube has a circular aperture within which a centring sleeve can be inserted that holds the pin on its free end after fixing its threaded end in the bone. The same Rancho cube also has a place where a grub screw can be inserted to tighten the sleeve on the pin (Smith & Nephew 2011). The sliding bars are composed of 12 holes as if they were twelve Rancho cubes stacked together. Such a configuration is not available commercially in such lengths and is unique to this design. Having the sliding bars with multiple fixation points allows the freedom of putting the pins in any of the holes if needed, provided the pins are all in the same long axis. Because the bars themselves are slotted and adapted for pin fixations, they would also be representing the bases for fixing the pins. If the rods were not accommodative for direct fixation of pins, then a separate base or clamp to hold the pins should be fixed to the sliding bars, but this would make the construct heavier and bulkier.

A spring-loaded mechanism will keep the sliding bars fully in the frames when the construct is in full extension, and allow the bars to slide out of the frames in flexion. This means in flexion the frames are effectively sliding central and the bars are sliding peripheral. In fact both the frames and the bars slide on each other, and each of them has a specific fixation mean. While the bars are fixed to the bone through four pins at least, and indirectly to the hinge through a spring-loaded mechanism, the frames instead are fixed directly to the hinge. This hinge is designed to have two mirror-image components; each component has multiple laminations that interconnect with each other when linking the two hinge components, giving a hinge that allows both flexion and extension. However, this hinge is designed to be rotationally stable due to the interconnections of the multiple metallic laminations.

A supportive collar is applied at the peripheral ends of the frames to give more structural stability to the frames, which makes them less likely to deform due to the load applied by the sliding bars within the frames when the construct moves.

Figure 3 also demonstrates the complete assembled sliding external fixation design in different positions, ranging from full extension to a flexion of 100 and 120 degrees respectively.

3.3.5 Operation of the Device (UK Patent Number: GB2519981)

Figure 4 shows the design in action after application on the upper limb, with two pins fixed to the bone proximal and two fixed distal to the elbow joint. It also demonstrates the bars sliding out of the frames in different degrees of flexion.

Operation of the device shows progressive degrees of bending of the elbow and the fixator's hinge. When the device is fully extended, the sliding bars are located close to the hinge. With progressive bending, the frames and the bars start to slide, and the promotional length of the fixator's arms start to increase proximal and distal to the hinge. On flexion, there is a proportional sliding movement between the frames and bars in which both look sliding out of each other. The bars slide further towards the periphery of the construct while the hinge and the attached frames slide more centrally. At maximum degrees of flexion, the central ends of the sliding bars may extend towards the peripheral ends of the frame members but never beyond the recoiling capacity of the spring-loaded mechanism, which would guide the construct back into extension by aiding the bars to slide back in the frames. The total sliding out is preferably between 25 and 30 cm, divided between the two arms of the external fixator on either side of the hinge. That means each rod would be sliding a maximum of 15 cm out of its corresponding frame on flexion and equally sliding back on extension.

In the clinical practice, such an external fixator is preferably made from a metallic material that is compatible with magnetic resonance imaging (MRI). A material like titanium would be suitable for this purpose, as it would allow magnetic resonance examination of the joint after the external fixator application, if needed. Furthermore, titanium is light weighted and provides an ideal smooth surface for the sliding mechanism to function with least possible resistance.

3.4 Prototype

3.4.1 Failed Prototype Assembly

Multiple attempts with different materials were made to create a functional prototype, and at least the first two of these failed. The original aim was to use the product design as the exact blueprint in creating the prototype, both in terms of the structure and the principles of function.

The very first attempt was by using a telescopic travel bag handle. As a sliding mechanism was present, connecting two of these sliding mechanisms with a hinge would provide the design, but this attempt led to rotational instability, as the sliding components glided because of a small difference in size between the inner and outer components of a typical telescopic handle. Their function is to drag the bag, but if one twists them they are indeed rotationally unstable. Therefore, the telescopic handles as a whole were not suitable for the experiment, and instead the outer hollow component of those sliding parts of the handle (which has square shaped cross-sectional profile) were chosen, and a separate but slightly smaller solid bars (which also has square shaped cross-sectional profile) were slid in to eliminate rotational instability. However, even that failed because the solid bars got jammed within the hollow components.

3.4.2 Successful Prototype Assembly

The design concept demonstrated the sliding mechanism by using bars with square cross-sections, and they appear as long bars of Rancho cubes stacked together and allowing the half pins to be inserted in any of the available holes. These specifications were difficult to meet when creating a handmade prototype, as the Rancho cubes come with a maximum of five holes and never in long bars. Furthermore, building an interconnected hinge needs factory-level machinery and precision as the interconnected components have to fit with each other and to stay concentric with the long central axis of the sliding frames and bars, both when stationary and during movement. Instead the prototype omitted the interconnected hinge and replaced it with an ordinary simple door hinge, and the sliding squared frames and rods were replaced with sliding blades and rails instead, based on commercially available window slides. Utilizing these modifications to the design left no disparity between the hinge's axis and the sliding mechanism's bars and frames longitudinal central axis. These changes to the original design have made the prototype simpler to assemble, and the main aim of applying a self-adjusting sliding external fixator without identification of the centre of rotation could be achieved.

A sliding external fixator prototype following the design's principles but not its exact shape and geometry, is handmade using different metal items including a pair of window slides, a basic door hinge, fixation bolts, fixation nuts, two sets of Rancho cubes, four grub screws, and four long pins with 0.35 cm cross-sectional diameters. Each of the window slides has two rail-like components representing the frames and inner sliding blades, which represent the rods. Each set of the Rancho cubes were fixed by bolts and nuts (in an upside down pattern) to the inner sliding blades of the window slides. The Rancho cubes were fixed to the sliding blades by applying the bolts from underneath the blades and by choosing bolt heads with a thin profile; therefore, there was no contact between the bolt's heads and the corresponding frame and impedance of the sliding mechanism was avoided.

The outer frames of the two window slides were linked to the door hinge through bolts and nuts in a single long axis, which enabled this construct to work as a sliding fixator. When the threaded ends of the pins are fixed in the bone, the free ends of those pins are inserted in the Rancho cubes within small sleeves and each is held with a grub screw. Subsequently, each side of the fixator will have two pins connected between the bone and the fixator.

The external fixator is applied to the arm with at least two pins proximal and two pins distal to the joint to ensure stability and also to ensure axial sliding movements during elbow function without rotational or translational element that may cause construct instability. Flexion and extension movements of the elbow happen in the sagittal plane, and so the pins are applied perpendicularly through the sagittal plan in the extensor surface of the bone proximal and distal to the elbow joint.

3.5 Research Design and Experimentation Plan

Research design may be explained as a common plan regarding the researcher's approach to answer the research query. In experimental research design the investigator manipulates one or more variables and estimates variation in other variables (Saunders, Lewis & Thornhill 2012).

This work will employ experimental research design using a handmade self-adjusting sliding external fixator prototype from basic tools to simulate the intended sliding mechanism. This prototype's application on upper limb specimens is used to study the design's theory in experimental settings.

3.5.1 Saw-Bone Experiment Plan

The handmade prototype described earlier shall be the sliding external fixator model that is to be applied over the elbow within an upper limb saw-bone model, with pins fixed on the posterior aspect of the humerus and ulna. The hinged part of the fixator is positioned behind the elbow joint. This application is intended to determine whether the fixator would be able to allow joint movement without identification of the centre of rotation, and to be able to maintain a congruent reduction if used after the joint is dislocated.

3.5.2 Cadaveric Experiment Plan

The same prototype external fixator will be used over the elbow of upper limb human cadaveric specimens, to primarily establish that the external fixator can be applied without identification of the centre of rotation, alongside its ability in maintaining reduction if used after elbow dislocation. Furthermore, to assess how much additional load can be tolerated by the construct after its application.

The planned steps for this research's design during the cadaveric testing are represented in Figure 5.

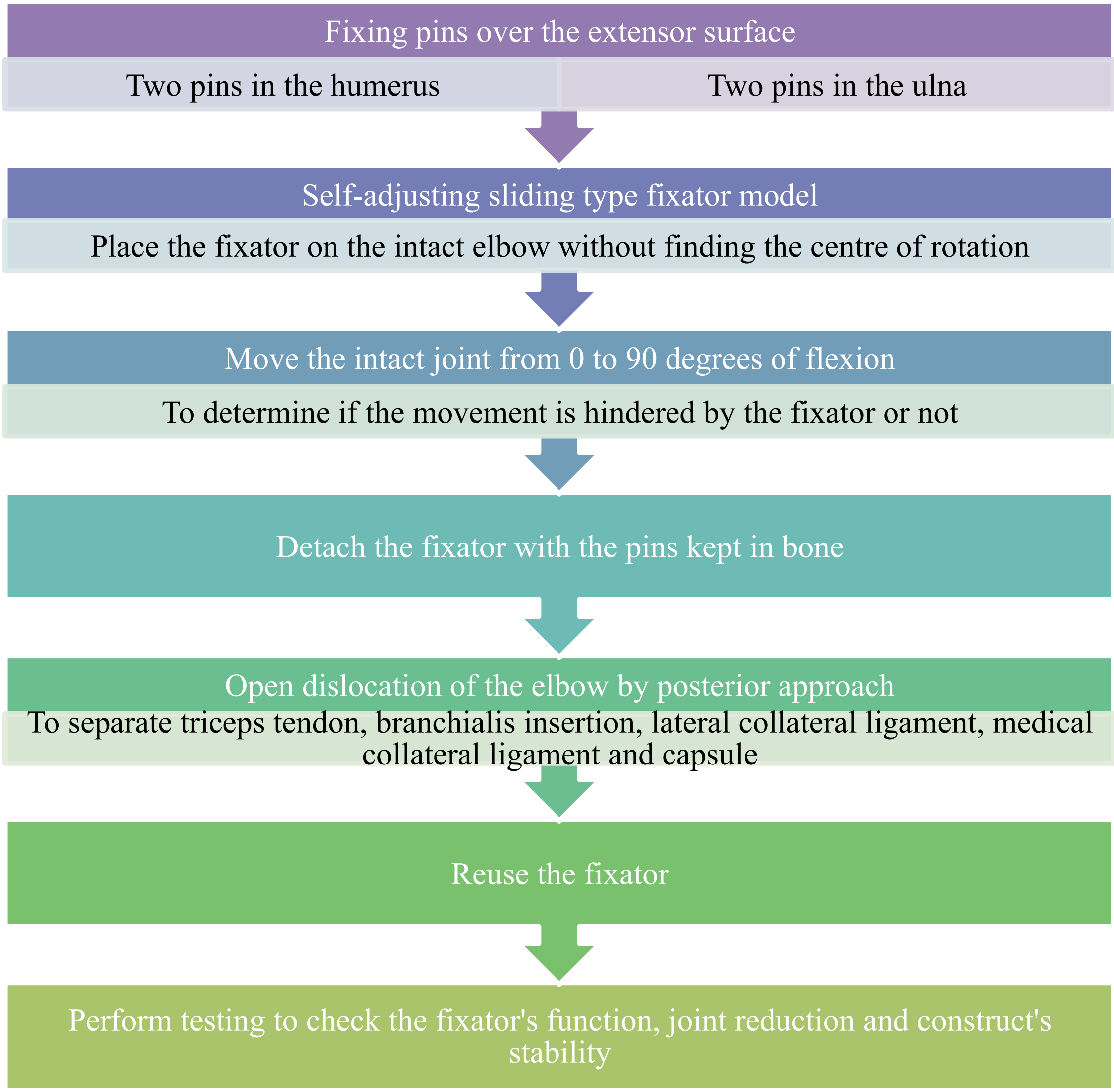


Figure 5. Flow diagram of the planned cadaveric testing.

Source: Author's own

3.6 Sampling Design

Purposive sampling technique is also called judgmental, subjective or selective sampling. In this technique, sampling is carried out according to the judgment of the investigator. It is one of the most cost-effective and time-effective sampling methods available. This type of sampling can be a suitable technique if the amount of primary data source is restricted. In purposive sampling, personal judgment needs to be used to choose cases that help answer research questions or achieve research objectives (Black 2010).

The sampling technique adopted for this work is a purposive sampling technique.

3.7 Data Collection Technique

Data collection can be divided into primary and secondary data collection techniques. Primary data is gathered directly by the investigator for some specific purpose. There is a higher degree of control for the investigator in primary data. The control might be over the study budgets, sample size, and sampling techniques. The accuracy may be controlled through increasing or decreasing the resources utilized for the data collection. Secondary data are the data gathered by a party not linked to the research analysis, having gathered these data for some other purpose and at a different time in the past (Creswell 2014).

Primary data used in this study is collected directly from testing the external fixator application on saw-bone and cadaveric human upper limb specimens. The primary data collected will be qualitative in nature. The secondary data to be employed in this research is the literature gathered on the relevant field.

3.8 Data Analysis and Interpretation

Data analysis and interpretation can signify the purpose of deductive as well as inductive logic to the study. Very frequently researchers depend on their experience of specific settings to be able to read the information given by the subjects involved in the study. This study used a qualitative approach for data collection, and the primary input of the results is from the application and function of the sliding external fixator prototype through saw-bone and cadaveric experimentations. The purpose of obtaining experimental results and outcomes would reflect a possible future clinical benefit in making the application of this type of external fixation easier and less demanding.

3.9 Ethical Considerations

Ethics are a cornerstone for carrying out efficient, meaningful and justifiable research. As such, the ethical behaviour of individual investigators is under unprecedented scrutiny. In today's society, any problems regarding ethical practices will negatively affect attitudes about science, and the abuses committed by a few are often the ones that receive widespread publicity (Trimble & Fisher 2006). Ethical considerations in research are critical. They reflect the norms or standards of conduct that distinguish between right and wrong, and establish the difference between acceptable as well as unacceptable behaviour on the part of the researcher.

Cadaveric experimentation was only permitted after the design and the patent were both submitted, and after the saw-bone experimentation outcome has shown a potential benefit.

3.10 Summary

This study has employed a qualitative research approach and an experimental research design based on saw-bone and cadaveric experiments, to generate outcomes that can explore the potential benefits of the self-adjusting sliding orthopaedic external fixator principle.

The nature of sampling technique involved is purposive or judgmental sampling, and the primary source of results is the set of outcomes gathered from the application and function of a prototype that represented the principles of the fixator.

Chapter 4. Experimentation and Discussion

4.1 Introduction

This chapter explains the details of the experimentation and provides the outcomes obtained using the self-adjusting elbow sliding orthopaedic external fixator prototype based on the patented design's concept. The relevant experiments performed are discussed in this chapter. These experiments were performed to bring out the usefulness of the prototype and also to satisfy the research's aims and objectives. The results obtained and the related discussions are also included in this chapter.

4.2 Experimentation

4.2.1 Saw-Bone Experiment

The major aim of performing a saw-bone experiment was to apply a sliding external fixator without having to identify the elbow centre of rotation and without the need to match it with the centre of rotation of the fixator's hinge. Furthermore, this experiment assessed the concentric mobility of the prototype on a saw-bone elbow joint when the joint was being passively mobilised through the arc of motion while the prototype sliding external fixator was connected to the ulna and the humerus. This experiment also analysed the ability of the prototype to maintain the reduction and the concentric movement when the model was devoid of the stabilising artificial joint capsule and ligaments.

At the time of pin fixation in the bone the prototype itself was used as a template for the pin site locations. The needed locations for these pins were marked over the posterior aspect of the humerus and the ulna before drilling the bone and applying the pins. When making these markings for the pin sites, locating the hinge of the prototype exactly behind the elbow at the mid-posterior aspect of the olecranon at the lever of the elbow joint was crucial. After making the drill holes in the saw-bone, two pins were inserted in the mid-posterior aspect of the humerus perpendicularly to the long axis of the humerus, and two pins were inserted in the mid-posterior aspect of the ulna over the subcutaneous border. The external fixator prototype was then loaded over those pins, so the pins were inserted in the planned positions within the corresponding Rancho cubes holes, and each of those pins were held with a centring sleeve and a grub screw (Figures 6 and 7).

With the recoiling mechanism in action the external fixator did not impede the joint movements between passive flexion and extension, before detaching the supportive synthetic ligaments. This step was not only a starting point, but it also helped making sure that the external fixator did not hinder the joint mobility despite not matching the centre of rotation. Furthermore the fixator was able to maintain joint reduction when it was devoid of supportive synthetic ligaments.

The saw-bone experiment explored the ability of the sliding mechanism of the fixator to function when the joint is stable with the synthetic ligamentous structures in place. Furthermore, it explored the ability to maintain the function of this sliding mechanism while keeping the joint congruent when the ligamentous structures were removed.

This experiment demonstrated the feasibility of applying the external fixator on the extensor surface of the elbow joint, with the sliding mechanism able to adjust for the movements in flexion and extension, with no need to identify the centre of rotation of the elbow joint. As the objectives of the saw-bone experiment were achieved, the results obtained through this experiment paved the way and gave enough justification to perform further cadaveric testing.

The pictures of saw-bone experiment are presented here:

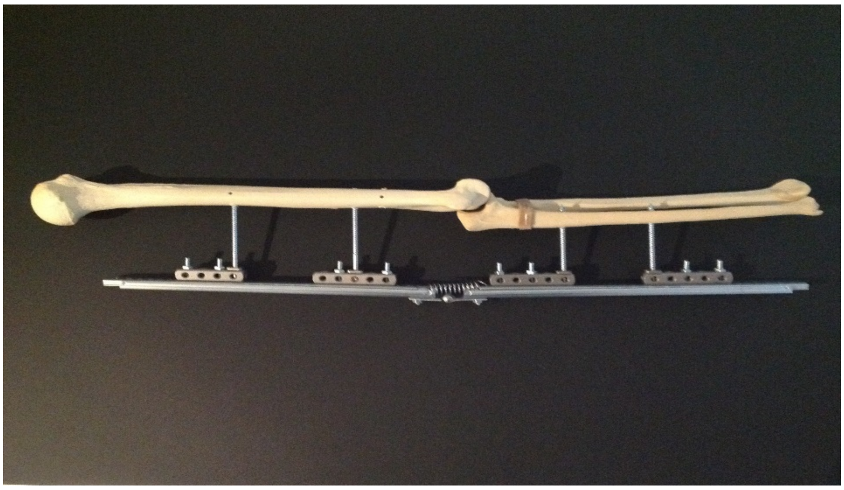


Figure 6. Saw-bone picture 1.

Source: Author's own

Figure 6 is a picture of the saw-bone experiment which shows the prototype applied to a saw-bone model over the extensor aspect of the elbow joint, while the elbow reduction is maintained in extension with the recoiling spring in action, despite the joint being void of ligaments. The pins were applied through the extensor surface, and the sliding fixator arms were retracted within each other on either side of the hinge as the construct is extended. Note that the hinge was located at the level of the elbow joint.

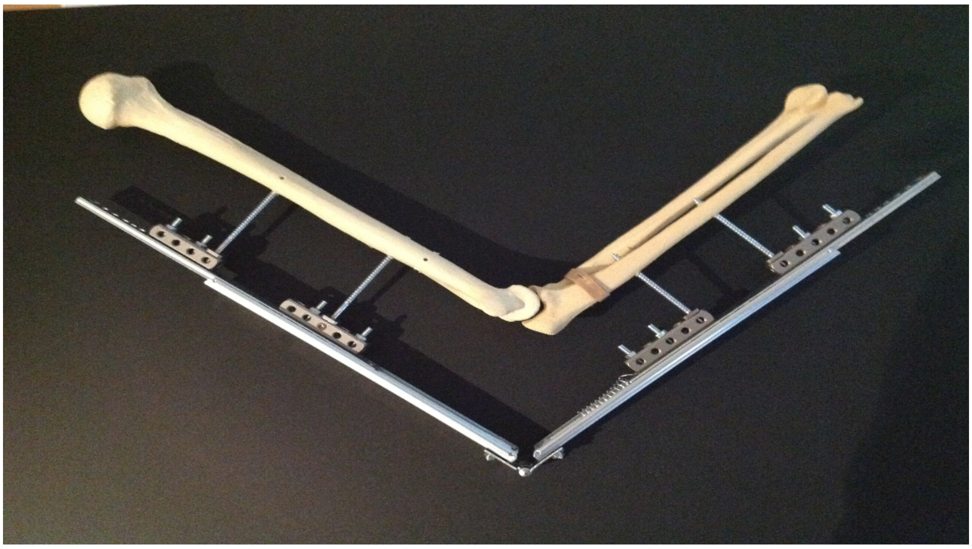


Figure 7. Saw-bone picture 2.

Source: Author’s own

Figure 7 is a picture of the saw-bone experiment, which demonstrates the saw-bone model in flexion, with the recoiling mechanism disabled by disconnecting the spring to keep the elbow in flexion allowing photography. The sliding fixator arms are shown extending out of each other on either side of the hinge as the construct is flexed.

4.2.2 Cadaveric Experiment

In this study, two fresh frozen cadaveric upper limb specimens were employed. The cadaveric specimens were thawed before the experiment. Three specimens were provided for the experiment; however, wrong pin application rendered one specimen not suitable for further testing. Each human cadaveric specimen was composted of an intact healthy upper limb (scapula to finger tips). Each specimen was connected to a vertically grappling metal clamp that was holding the scapula, while the elbow was kept flexed over the edge of a mortuary trolley, with the posterior extensor surface of the elbow facing upwards. The specimens were examined to exclude signs of any previous surgery, elbow stiffness, pathological elbow instability, and any other pathology such as severe deformity that would affect the flow of the experiment.

During the saw-bone experiment, handling the upper limb sample is easier as it is light in weight and lacks biological tissue cover. The cadaveric experimentation was a step further after the saw-bone experimentation, which was used to test whether the results generated by the saw-bone experiment are actually applicable to human tissue and joints of normal size and mass. Although the experiment worked well on the saw-bone model, as the intact human elbow is more stable, the possibility of the sliding external fixator jamming the intact joint from mobilisation could not be ruled out. Therefore, the intention was to test the sliding mechanism functionality both on intact and dislocated elbow joints.

The cadaveric experiment was performed to assess the possibility of applying a sliding external fixator on the extensor surface of an intact elbow without identifying the centre of rotation and also without radiographic guidance. This was aimed to determine whether the prototype application would not obstruct the joint mobility in case of incongruity between the centre of rotation of the fixator and the intact elbow before testing it on dislocated elbows. Application on an intact joint tests the ability of the sliding fixator to allow joint movements because if the sliding mechanism can function when joint mobility is not hindered, then it can accommodate to follow the elbow's intact centre of rotation as if they are one unit.

The prototype was first used to template the pin positions after considering the applied regional anatomy to avoid approaching any neurovascular structure with those pins, very much like the steps of an external fixation application in current clinical practice.

After choosing the four pin insertion sites, two stab incisions were made in the humerus in-line with its long axis over the mid-posterior aspect, followed with blunt dissection to approach the posterior bony cortex of the humerus, without injuring the radial nerve. Drill holes were performed, and corresponding pins were inserted. Then two stab wounds were made over the posterior aspect of the ulna in-line with the long axis created by the two pins of the humerus. The pins were placed in the ulna over the posterior aspect but slightly lateral to the exact mid-posterior aspect due to the curvature of the ulna in the coronal plane observed during the experiment. The most central pins were applied at about 8 cm away from the elbow joint, whereas the peripheral ones were about 15 cm away.

After the application of all the four pins, the free edges of the pins were connected to the external fixator prototype within the pre-planned locations. The first major step in the cadaveric experiment was testing the application of the external fixator prototype over an intact elbow without establishing the centre of rotation. The hinge had to be kept at the back of the elbow, at the mid-posterior aspect of the olecranon and at the level of elbow. This construct was built without using radiological guidance in identifying the centre of rotation and without dislocating the elbow joint, yet the fixator did not impede the joint movements and the elbow was mobilised through the movement arc from full extension to 90 degrees of flexion, without being jammed or hindered by the intact elbow. The external fixator arms on either side of the hinge did not have enough sliding length to allow total flexion of the construct beyond 90 degrees.

The second major step was to test the same fixator on a dislocated elbow joint. The fixator was removed from the intact elbow joint while keeping the pins in position. Surgical dislocation of the elbow was performed, through a 20 cm posterior incision centred over the mid-posterior aspect of the olecranon. After skin and soft tissue dissection, the triceps tendon was completely detached from the olecranon; followed by complete surgical detachment of the medial collateral ligament, lateral collateral ligament, brachialis muscle attachment and joint capsule. This resulted in a completely dislocated elbow. After this surgical dislocation, the experiment was continued by reapplication of the external fixator and secured to the pins, which were left in position. The fixator was still capable of keeping the joint congruent, right through the movement arc of 0-90 degrees. A 10 N distracting force was applied over the most distal pin and did not displace the joint while the construct was in full extension. However, between 10 and 15 N of distraction force on a fully extended elbow, the construct showed observable displacement at the joint level. Unfortunately the construct of the actual clamp holding the upper limb specimen did not withstand applying the same 10 N of distraction while the elbow was in 90 degrees of flexion, as the specimen started slipping off the clamp. More attention should have been given to repeated testing with measured distraction in different directions.

During pin application in the cadaveric experiment, mismatch between the long axis of the arm and the long axis of the fixator was noticed, and so after inserting the pins in the humerus while loading the external fixator, the pins inserted in the ulna had to be shifted about 0.25 cm lateral to the mid-point of the posterior aspect of the ulnar border. This was attributed to the curvature of the ulna in the coronal plane, however a more important reason is failing to incorporate the carrying angle into the external fixator's hinge.

The cadaveric experiment was repeated on a second specimen in the same sequence and resulted in the same outcome. The following pictures demonstrate the different steps carried out in the cadaveric experiment.

Figure 8. Cadaveric picture 1.

Source: Author's own

Figure 8 shows the external fixator applied to the extensor surface of a fully extended intact elbow joint with the pins anchored to the ulna and the humerus, through stab wounds in the soft tissues, and connected to the sliding fixator by being secured in the allocated Rancho cubes. Note that the external fixator's hinge is at the mid-posterior aspect of the olecranon and at the level of the elbow joint.

Figure 9. Cadaveric picture 2.

Source: Author's own

Figure 9 shows the external fixator applied to the extensor surface of the intact elbow joint at 90 degrees of elbow flexion. Note that the external fixator's hinge is still at the mid-posterior aspect of the olecranon and at the level of the elbow joint. However, the distance between the hinge and the most adjacent pins has increased due to the sliding mechanism of the external fixator.

Figure 10. Cadaveric picture 3.

Source: Author's own

Figure 10 shows the elbow after it has undergone a complete surgical dislocation and after the external fixator has been completely removed. The pins were left in the same location connected to the bone for subsequent reapplication of the fixator. Note that the dislocated elbow was subjected to distractive force in flexion to demonstrate the gap created between the humerus and the ulna, reflecting the extent of the surgical dislocation achieved.

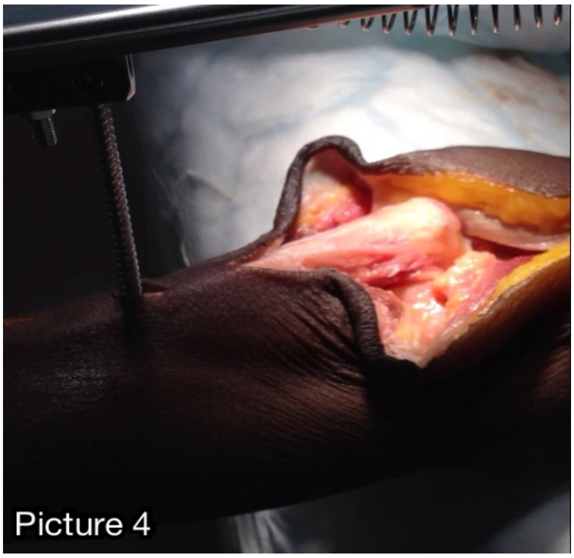


Figure 11. Cadaveric picture 4.

Source: Author’s own

Figure 11 shows that the external fixator has been reconnected to the pins over the previously dislocated elbow. Reapplying the external fixator has managed to keep the elbow joint reduced again, while the elbow is in full extension. Note that the olecranon is fully engaged with humerus reflecting restoration of the bony congruency after the fixator was reapplied, while the joint was devoid of any intact ligaments.

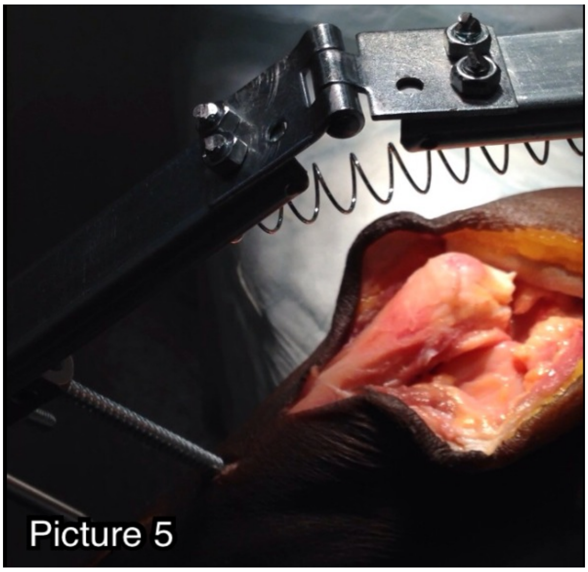


Figure 12. Cadaveric picture 5.

Source: Author’s own

Figure 12 shows the external fixator reapplied over the pins on an elbow, which has undergone a complete surgical dislocation previously. The external fixator has managed to maintain the elbow reduced not only in extension but also in flexion. Note that the gap between the humerus and the ulna seen with the surgical dislocation is now completely abolished after the fixator was reapplied.

4.3 Results

The self-adjusting sliding orthopaedic external fixator product design has proven its novelty by being successfully patented (UK Patent Number: GB2519981), which is published through the Intellectual Property Office (Mohammed 2015). In addition, this work has been summarized as a poster presentation (Mohammed 2018) and a published article (Mohammed & Frostick 2015).

The saw-bone experiment proved that the sliding mechanism functions over the elbow both before and after dislocation, but the stability of the saw-bone specimen itself is not comparable to the complexity of a human elbow joint, so these findings were proven again by the cadaveric testing.

The results obtained through the cadaveric experiment proved that the external fixator does not impede the movements of flexion and extension of the elbow joint, even when it is applied over an intact elbow joint and prior to the surgical dislocation. Application of the fixator over an intact joint was not merely an experimental starting point but rather an important test to establish the functionality of the sliding mechanism despite applying it on an intact joint that by itself cannot change its centre of rotation. In other words, the intact joint cannot undergo subluxation to adjust for the external fixator movement, which means the only possible conclusion is that the sliding mechanism can function and self-adjust to accommodate the elbow joint movements.

Surgical dislocation is an extreme form of dislocation, as in practical conditions patients would rarely present with an open dislocation on the elbow that would resemble the surgical dislocation performed in this work, as they usually present with comparatively less severe elbow disruptions. The fixator used in this work has proved to function on the surgically dislocated human elbow joint, which means it would be functional on less severe dislocations. The fixator was able to maintain the concentric reduction between full extension and 90 degrees of flexion.

A 10 N worth of distractive force in full extension could be tolerated by the construct of the sliding external fixator and the cadaveric elbow but was not tolerated in flexion because in flexion the weight of the forearm also comes into play along with the effect of gravity.

Ultimately this test has proved that the application of this external fixator does allow joint movements, without the need to identify the centre of rotation, and so without the need for radiography.

4.4 Discussion

A simple elbow dislocation is commonly dealt with reduction and stabilisation. The primary aim of the treatment is to achieve elbow stability and early mobilisation. The conflict arises between using internal or external fixator as the first line of treatment (Mader, Dargel & Gausepohl 2014).

When there is a failure in joint restoration, the result would usually be in a reduced function, stiffness, articular degeneration, arthritic changes and instability. Immobilisation of the elbow joint in adults for more than 2 weeks will possibly result in stiffness. Thus it is very important to mobilise the dislocated elbow joint after reduction and congruent relocation. When there is a fracture associated with the elbow dislocation, it can be treated with open reduction and internal fixation followed by early mobilisation as early as the pain allows joint mobility to prevent stiffness and to maintain a functional level of movements (Taylor et al. 2012). Although there are various options in treating elbow dislocations, no particular treatment procedure is still totally preferred by the medical professionals as every method of treatment has its own advantages and disadvantages (Hildebrand, Patterson & King 1999).

Open reduction and internal fixation with plating is a well-known accepted treatment for elbow fractures. This aims to achieve pain-free elbow motion and restoration of full function, and the surgery should be done within 24-48 hours. Proper management of the open wounds must be ensured to avoid the possibility of infections. Wound type, time taken for the surgery, level of contamination and associated vascular injuries should also be considered (Gupta et al. 2014).

External fixation is another treatment option to provide bony stability with pins or wires. External fixators possess various advantages like causing minimal damage to the periosteal blood supply, usefulness in stabilising open fractures, reduced disturbance to the soft tissue cover and the ability to adjust construct rigidity without further surgery (Fragomen & Rozbruch 2007).

There are many orthopaedic external fixators available that can be used to stabilise the elbow. These fixators can be one sided, that is monolateral, or circular so they can provide stability in more than one plane, which makes them more rigid than monolateral fixators. When treating a joint with external fixation it can be used as a spanning fixator that spans the joint by fixing the bone proximal and distal without any hinge in between, so joint mobilisation cannot be done while the fixator is on. The other option is to apply an external fixator that has one or multiple hinges to allow joint mobilisation while the external fixator is on. This means external fixators can either be static or dynamic. Dynamic stabilisation provides fracture stability while allowing joint mobilisation for rehabilitation and prevention of stiffness with earlier restoration of function (Jeon, Kim & Kim 2008).

Not all ligaments are disrupted in all elbow dislocations, as it depends on the severity of the dislocation. So in simple elbow dislocations, there might be mild ligamentous injury, whereas complex dislocations are more likely to have multiple associated ligamentous injuries (Josefsson, Johnell & Wendeberg 1987).

During elbow dislocation the mechanical injury starts from the lateral and progresses to medial position. In the first stage, the lateral collateral ligament complex gets affected, which involves the radial collateral ligament, the lateral ulnar collateral ligament and the annular ligament. The second stage will be associated with injuries in the anterior capsular structures. In the third stage, the mechanical injury leads to injury of the medial soft tissue structures, as the forces have now migrated medially (O'Driscoll, Morrey & Korinek 1992). Collateral ligament reconstruction and repair must be anatomical in order to provide unobstructed movements of elbow. The instability or stiffness after the repair is primarily due to the mal-positioning of the non-isometric medial ulnar collateral ligament or the isometric lateral collateral ligament and also dependent on the position of the elbow during the process of tensioning the repair (O'Driscoll 1999).

Furthermore, the severity of the ligamentous injury may not allow primary repair and may necessitate augmentation with free tendon graft or skeletal support with hinged external fixators. Hinged external fixators must be applied precisely aligned with the centre of rotation of the involved joint (Ring, Bruinsma & Jupiter 2014).

Achieving static stability of the dislocated elbow is technically simpler than dynamic stabilisation, however it has increased chances of elbow stiffness. This is due to the prolonged immobilisation after dislocation, which prevents early functional rehabilitation (De Haan et al. 2010).

When applying a dynamic external fixator to the elbow joint, its centre of rotation has to match that of the elbow joint, so when the joint and the fixator's hinge move together throughout the arc of movement, they maintain the centre of rotation between them perfectly matched. If the two are not concentric, the join cannot remain congruently reduced when mobilised (Jupiter & Ring 2002).

Identifying the centre of rotation is not an everyday trauma procedure, so it is better achievable in the hands of the experts, while having an external fixator applied to the elbow joint is not a common procedure anyway means very few experts can achieve the match of centre of rotation properly. In addition to the need of good experience in external fixation, multiple intra-operative radiological exposures are mandatory in anterior to posterior and medial to lateral directions to accurately identify the centre of rotation (Potini et al. 2015).

A dislocated elbow treated with prolonged immobilisation will end up in stiffness (Schippinger et al. 1999). Using a monolateral external fixator is a good option to prevent stiffness. When such fixator is applied to the elbow it has to be placed on the lateral side, after identifying the centre of rotation. First, a guide wire is passed through the centre of rotation and then the external fixator is built on it. The guide wire has to be positioned in the centre of the capitellum on the lateral view and also has to be central when it is passed through the trochlea. Additionally it has to be parallel to the joint surface on the anterior to posterior radiographic view (Orthofix 2019).

If the application is not concentric, there are two main scenarios. First, if the elbow is very unstable it will be forced to change its anatomic centre of rotation and will follow the centre of rotation of the improperly placed fixator. Subsequently, the joint will undergo subluxation and may dislocate when mobilised. In the second scenario the joint still has some inherent stability. In this case the inherent joint stability and the external fixator will oppose each other with different centres of rotation and the whole construct can jam, leading to reduced mobility and eventually to stiffness.

The concept presented in this thesis is an effort to overcome the technical issues described earlier with the current external fixation techniques. It is unique to this work to apply the external fixator on the extensor surface of the elbow, with the proximal pins through the mid-posterior aspect of the humerus and the distal pins through the mid- posterior aspect of the ulna, while keeping the hinge at the joint level. The external fixator itself can be used as a template to guide inserting the proximal pins in the same alignment to the distal pins, and this will ensure that the whole of the external fixator and its sliding mechanism stay on one long axis to prevent impedance to the sliding mechanism. With this design there is no need for radiological guidance and the application should be easier to handle by a general orthopaedic surgeon (Mohammed & Frostick 2015).

Chapter 5. Conclusions and Future Work

5.1 Introduction

This chapter provides conclusions from the work involving the presented design of a self-adjusting sliding orthopaedic external fixator for the treatment of dislocated elbow joints and summarizes the advantages of using such a fixator. The chapter also discusses the limitations of this work and addresses the concepts needed for future work.

5.2 Conclusion

5.2.1 Elbow Dislocations and External Fixation

Elbow dislocations can be repaired and reconstructed by using various techniques including open reduction and internal fixation, closed reduction and external fixation or even total joint replacement. But in the case of elbow dislocation, total joint replacements have many possible complications such as developing fractures around the implant, implant loosening, nerve palsy, infection and triceps insufficiency (Kim et al. 2011).

When a dislocated elbow undergoes reconstruction through open reduction or closed reduction, it can result in stiffness. In contrast with open techniques, external fixation can allow earlier rehabilitation and support joint mobilisation at an early stage. This earlier mobilisation when using external fixation can reduce the chances of stiffness. Monolateral external fixators were used to supplement open reduction and internal fixation and were found to be effective, reliable and well tolerated by the patients (Ouyang et al. 2013).

External fixators are better suited for acute instability, chronic instability, terrible triad injuries, fracture dislocations and prolonged period of ligamentous healing (Panchal &

Murthi 2012). They have several advantages such as maintaining a congruent, stable elbow joint and allowing healing of acute or chronic soft tissue injuries, while giving chance for mobilisation relative to the axis of the external fixator (Chen & Julka 2010).

Although these fixators are suitable for unstable simple or complex elbow dislocations, wound healing can be affected due to factors like diabetes or additional medications like steroids. They are mainly advised for patients who are considered to be unsuitable for open surgical intervention or prolonged surgical procedures (Harris, Bishop & Bernard 2015).

5.2.2 Self-Adjusting Sliding External Fixator

There are various kinds of external fixators such as hinged external fixators (Bigazzi et al. 2015; Yu et al. 2015; Zilkens et al. 2009), circular/ring fixators (Ilizarov technique) (Bari et al. 2015; Chida et al. 2016; Nemade et al. 2015) and Joshi's External Stabilisation System (JESS)-type fixators (Ghosh et al. 2015; Saha, Ray & Behara 2016).

Treating a joint fracture-dislocation is not new to trauma and orthopaedic surgery irrespective of the implant or method being used. However, each implant has its philosophy and reasoning. When it comes to external fixation there are different reasons for its use and there are different types and techniques involved. The scope of this work is to promote an approach to add another technique to external fixation, making it a less demanding procedure and so more readily available when needed.

The technique introduced in this study is a self-adjusting sliding external fixator (UK Patent Number: GB2519981) that can be used when internal fixation should be avoided, for example, due to associated soft tissue injuries. Experiments have shown that the proposed design satisfies the objectives of the study. The cadaveric experiment is considered to be the ideal procedure for testing the new prototype before attempting to introduce this new technique at the clinical level. When elbow dislocations are treated with external fixation, the surgical procedure needs to be less demanding and that can be possibly addressed by this design of external fixation (Mohammed & Frostick 2015).

The design used in the present study is a novel self-adjusting sliding external fixator, which allows joint mobilisation that would help in early rehabilitation. The application of this design does not need a special experience in identifying the centre of rotation and does not need radiological guidance, which means there are no radiological hazards to the patient or to the surgical team.

5.3 Future Work

The recoiling mechanism used within the sliding fixator principle can be made adjustable to match the tension needed in each individual, as the load would differ from one patient to another, according to the weight of the limb involved. It has to be taken into consideration that subjects with different body mass indices can have different forearm weight, which would load the fixator especially in the standing position due to the gravitational effect. The recoiling mechanism needs to be adjustable to accommodate different loads, but this might need more space within the external fixator close to the hinge, and this very space is essential to accommodate the sliding mechanism especially the recoiling of the rods in extension.

The principles of application of a self-adjusting external fixator on the extensor surface of a joint would not be unique to the elbow articulation, as the same principle can be applied to other joints while taking into account different joint sizes and regional anatomical considerations. Application on other joints would also mandate that the hinge must be kept on the extensor surface at the level where the joint is, which is clinically easier to do than finding the centre of rotation.

The joint level can be easily identified through clinical examination of a large joint like the elbow or even smaller joints. However, using a needle intra-operatively to feel for the joint level is an option in small joints like the interphalangeal joint. Applying a sliding external fixator to manage a dislocated interphalangeal joint is another location where the principles of this design could be used. The fixator has to be applied with the hinge on the extensor side of the joint, at the mid-dorsal aspect of the interphalangeal joint being treated. If such a fixator is to be applied over the interphalangeal joint, obviously it has to be made in a smaller version that fits the joint size in question. However, there are more important considerations when addressing the interphalangeal joint as the extensor tendon lies all the way over the extensor surface, unlike the elbow where the extensor tendon is closer to the olecranon, so it can be away from pin site insertion. In order to protect the extensor tendon during a potential application over an interphalangeal joint, the pins have to be applied differently. Instead of being passed perpendicularly from the extensor towards the flexor surfaces of the bone, they have to be accommodated with half rings or small arches that are themselves connected to the sliding base. Such arches allow fixation of the bone on the sides of the extensor tendon while keeping the hinge over the midpoint of the extensor surface, very much like using a miniature half a circle of a ring fixator to hold the pins applied obliquely through the dorsal aspect of the joint avoiding the extensor tendon. Then these half rings are connected to the arms of a sliding external fixator.

The sliding mechanism can be presented differently for example by using blade-like bars that slide over rails, each of which is rectangular in cross-section, so the rails act instead of the frames and get hinged behind the joint, and the rectangular blades slide over the rails and provide a place for pin fixation. Although this would be similar to the prototype used, this concept was not included in the patent.

5.4 Limitations

The prototype used in this work was a handmade product from commercially available items, which aimed to reflect the principles of the design's advocated function. Manufacturing a prototype that follows both the design's function and geometry needs a factory-level machinery to create a more stable sliding fixator. This fixator would have a hinge designed to prevent rotational instability and sliding arms that do not became rotationally less stable in full flexion, as the physical lever arm on either side of the hinge becomes longer.

This work presented a sliding external fixator design, which addresses the difficulties faced while applying an external fixator over the elbow joint. However, it does not address anatomical variability between different individuals. During the cadaveric experiment and when applying the pins in the ulna, they drifted laterally over the posterior aspect of the ulna, which was thought to be due to the difference in curvature between the ulnas of different specimens. While examining the cadaveric specimens, it was noted that ulnar curvature especially in the coronal plane came in different degrees of coronal concavity, a problem that is not addressed by the design. Similarly the ulnar pins had to be displaced laterally over the posterior aspect of the ulna, which means that the design did not address the anatomical carrying angle of the elbow. This angle could have been easily incorporated into the design at the very beginning by fixing the two arms of the external fixator to the hinge at an angle rather than in a single long axis when the fixator is in full extension.

Multidirectional clamps that can accommodate fixation of the free end of the pins irrespective of their fixation position in the bone would have been beneficial, which means even if there is bony deformity the pins can be fixed without using the fixator as a template. Applying the fixator would then become much easier, as it could secure the pins even if they were not in the same long axis.

Fractured bony buttress and severe bony fragmentation were not addressed in this work, as that would be more complex to test than pure ligamentous elbow dislocations. If the fracture compromises the bony buttress and inherent bony congruency is lost, then the recoiling mechanism would make the fixator collapse towards the elbow, unless the recoiling mechanism is redesigned to function also as a distractive apparatus that prevents the collapse of the two arms of the sliding fixator on either side of the hinge.

Repeated testing with different weights in different directions would have been ideal to enrich the cadaveric testing results.

References

Bari, MM., Shahidul, I., Shetu, NH. and Mahfezur, RM., (2015) ‘Treatment of neglected elbow dislocation using Ilizarov ring fixator’. *MedCrave Online Journal of Orthopaedics & Rheumatology*, [online] 3, (5) pp.1-4. Available at <https://doi.org/10.15406/mojor.2015.03.00107> [Accessed 24 August 2019]

Bigazzi, P., Biondi, M., Corvi, A., Pfanner, S., Checcucci, G. and Ceruso, M. (2015) ‘A new autocentering hinged external fixator of the elbow: A device that stabilises the elbow axis without use of the articular pin’. *Journal of Shoulder and Elbow Surgery* 24, pp.1197-1205.

Bilezikian, J., Raisz, L. and Rodan, G. (2002) *Principles of bone biology*. 2 end. California: Academic Press.

Black, K. (2010) *Business statistics: Contemporary decision-making*. 6 edn. Jefferson: John Wiley & Sons.

Burg, A., Berenstein, M., Engel, J., Luria, T., Salai, M., Dudkiewicz, I. and Velkes, S. (2011) ‘Fractures of the distal humerus in elderly patients treated with a ring fixator’. *International Orthopaedics* 35, pp.101-106.

Celli, A., Celli, L. and Morrey BF. (2008) *Treatment of Elbow Lesions*. 1 edn. New York: Springer.

Chen, NC. and Julka, A. (2010) ‘Hinged external fixation of the elbow’. *Hand Clinics* 26, pp.423-433.

Chida, S., Nozaka, K., Miyakoshi, N., Yamada, S., Miyamoto, S., Nagasawa, H., Kijima, H., Sugimura, Y. and Shimada, Y. (2016) ‘Comminuted distal humeral fracture treated using the Ilizarov technique in a patient with rheumatoid arthritis and osteoporosis’. *Trauma Case Reports* 3, pp.7-11.

Creswell, JW. (2014). *Research design: qualitative, quantitative, and mixed methods approach*. 4 edn. California: Sage Publications.

De Haan, J., Schep, NW., Tuinebreijer, WE., Patka, P. and Den Hartog, D. (2010) ‘Simple elbow dislocations: A systematic review of the literature’. *Archives of Orthopaedic and Trauma Surgery* 130 (2), pp.241-249.

Dyer, G. and Ring, D. (2013) ‘Terrible triad fracture-dislocations of the elbow’. *Operative techniques in Orthopaedics* 23 (4), pp.198-204.

Englert, C., Zellner, J., Koller, M., Nerlich, M. and Lenich, A. (2013) ‘Elbow dislocations: A review ranging from soft tissue injuries to complex elbow fracture dislocations'. *Advances in Orthopaedics* [online] 13, pp.1-11. Available at <http://dx.doi.org/10.1155/2013/951397> [Accessed: 13 September 2017]

Ferenac M., Hart, R. and Kozak, T., (2013) 'Hinged external fixation in orthopaedic and trauma surgery of the elbow'. *Acta Chirurgiae Orthopaedicae et Traumatologiae Cechoslovaca* 80, (6), pp.391-395.

Fornalski, S., Gupta, R. and Lee, TQ. (2003) 'Anatomy and biomechanics of the elbow joint'. *Techniques in Hand and Upper Extremity Surgery* 7 (4), pp.168-178.

Fragomen, AT. and Rozbruch, SRR. (2007) 'The mechanics of external fixation'. *The Musculoskeletal Journal of Hospital for Special Surgery* [online] 3, (1) pp.13-29. Available at <https://doi.org/10.1007/s11420-006-9025-0> [Accessed 24 August 2019]

Gajendran, VK. and Bishop, JA. (2014) 'Terrible triad elbow fracture-dislocation with triceps and flexor-pronator mass avulsion'. *Case report* 38 (2), pp.143-146.

Ghosh, S., Patar, M., Chaudhuri, A., Datta, S., Banerjee, D. and Mitra UK. (2015) 'Management of supracondylar fracture of humerus with JESS in adults'. *Journal of the Scientific Society* 42 (1), pp.16-20.

Gupta, U., Gupta, S., Agrawal, G., Gandotra, A. and Pathania, VP. (2014) 'Surgical management of compound distal humerus fracture by JESS external fixator'. *Journal of Evolution of Medical and Dental Sciences* 3 (19), pp.5352-5366.

Harris M., Bishop, T. and Bernard, J. (2015) 'Unstable elbow dislocations: The description and cadaveric feasibility study of a new surgical technique'. *Société Internationale de Chirurgie Orthopédique et de Traumatologie Journal* 1, pp. 23.

Hildebrand, KA., Patterson, SD. and King, GJ. (1999) 'Acute elbow dislocations: simple and complex'. *Orthopaedic Clinics of North America* 30 (1), pp.63-79.

Hopf, JC., Berger, V., Krieglstein, CF., Muller, LP. and Koslowsky T.C. (2015) 'Treatment of unstable elbow dislocations with hinged elbow fixations subjective and objective results'. *Journal of Shoulder and Elbow Surgery* 24, pp.250-257.

Iordens, GI., Den Hartog, D., Van Lieshout, EM., Tuinebreijer, WE., De Haan, J., Patka, P., Verhofstad, MH. and Schep, NW. (2015) 'Good functional recovery of complex elbow dislocations treated with hinged external fixation: A multicenter prospective study'. *Clinical Orthopaedics and Related Res*earch 473 (4), pp.1451-1461.

Jeon, IH., Kim, SY. and Kim, PT. (2008) 'Primary ligament repair for elbow dislocation'. *Keio Journal of Medicine* 57 (2), pp.99-104.

Josefsson, PO., Johnell, O. and Wendeberg, B. (1987) ‘Ligamentous injuries in dislocations of the elbow joint’. *Clinical Orthopaedics and Related Research* 221, pp.221-225.

Jupiter, JB. and Ring, D. (2002) ‘Treatment of unreduced elbow dislocations with hinged external fixation’. *Journal of Bone and Joint Surgery-American* 84-A (9), pp.1630-1635.

Kailash, S. and Shanmuganathan, S. (2017) ‘Anterior dislocation of elbow with neurovascular injury: A rare case report’. *Journal of Orthopaedic Case Reports* 7 (1), pp.91-94.

Kalfas, I. H. (2001) ‘Principles of bone healing’. *Journal of Neurosurgery* 10 (4), pp.1-4.

Kamrani, RS., Farhadi, L. and Zanjani, LO. (2015) ‘Old unreduced elbow fracture and fracture dislocation: treatment with open reduction and hinge external fixation’. *Shafa Orthopaedic Journal* [online] 2, (2) pp.1-6. Available at <https://doi.org/10.17795/soj-1893> [Accessed 24 August 2019]

Kanakaraddi, S. (2013) ‘Primary total elbow replacement in a patient with old unreduced complex posterior elbow dislocation’. *Bulletin of the Hospital for Joint Diseases* 71 (4), pp.294-296.

Kazi, S., Keche, H., Joshi, P. and Wanjari, A. (2017) ‘The comparison and evaluation of carrying angle of elbow with anthropometric measurements in both sexes’. *International Journal of Anatomy and Research* [online] 5, (4.3) pp.4686-4690. Available at <https://doi.org/10.16965/ijar.2017.443> [Accessed 24 August 2019]

Kim, JM., Mudgal, CS., Konopka, JF. and Jupiter, JB. (2011) ‘Complications of total elbow arthroplasty’. *Journal of the American Academy of Orthopaedic Surgeons* 19 (6), pp.328-339.

Kumar, R., Shekhawat, V., Sankhala, SS. and Bijarnia I. (2014) ‘Anterior dislocation of elbow joint-case report of a rare injury’. *Journal of Orthopaedic Case Reports* 4 (3), pp.16-18.

Mader, K., Dargel, J. and Gausepohl, T. (2014) *Fracture dislocations of the elbow: The elbow fixator concept.* [online] Berlin: Springer. Available at <https://doi.org/10.1007/978-3-642-34746-7_74> [Accessed 27 August 2019]

Malagelada, F., Dalmau-Pastor, M., Vega, J. and Golanó, P. (2014) *Elbow anatomy* [online] Berlin: Springer. Available at <https://doi.org/10.1007/978-3-642-36801-1_38-1> [Accessed 13 September 2017]

Maniscalco, P., Pizzoli, AL., Renzi Brivio, L. and Caforio, M. (2014) ‘Hinged external fixation for complex fracture-dislocation of the elbow in elderly people’. *Injury International Journal* 45, pp. 53-57.

McCabe, MP. and Savoie, FH. (2012) ‘Simple elbow dislocations: Evaluation, management, and outcomes’. *Physician and Sportsmedicine* 40 (1), pp.60-71.

Miller, M., Thomson, S. and Hart, J. (2012) *Review of orthopaedics*. 6 edn. Philadelphia: Saunders.

Mohammed, AA. (2015) *Sliding external fixator patent GB2519981* [online] UK: Intellectual Property Office. Available at <https://www.ipo.gov.uk/p-find-publication.htm > [Accessed: 26 July 2019]

Mohammed, AA. and Frostick, SP. (2015) ‘Sliding external fixator: A product design and cadaveric experiment’. *Musculoskeletal Surgery* [online] 99, (1) pp.27-31. Available at <https://doi.org/10.1007/s12306-014-0329-9> [Accessed 24 August 2019]

Mohammed, AA. (2018) ‘Sliding external fixator: A product design and cadaveric experiment’. *Orthopaedic Proceedings* [online] 98-B, (9) pp.49. Available at: <https://online.boneandjoint.org.uk/doi/abs/10.1302/1358-992X.98BSUPP_9.ISTA2015-049> [Accessed: 26 July 2019]

Monreal, R. (2016). ‘Treatment of intertrochanteric hip fractures in elderly high-risk patients with external fixation’. *Orthopaedics and Rheumatology Open Access Journal* 3 (2), pp.1-3.

Müller, M.E., Nazarian S. and Koch, P. (1990) *The comprehensive classification of fractures of long bones*. New York: Springer.

Nemade, PS., Dash, KK., Patwardhan ,PY. and Londhe, PV. (2015) ‘Use of Ilizarov fixator for grade III B open olecranon fracture: A case report and surgical technique’. *Journal of Orthopaedic Case Reports* [online] 5, (1) pp.19-22. Available at <doi: 10.13107/jocr.2250-0685.246> [Accessed 26 August 2019]

O’Driscoll, SW., Morrey, BF., Korinek, S. and An, KN. (1992) ‘Elbow subluxation and dislocation. A spectrum of instability’. *Clinical Orthopaedics and Related Research* 280, pp.186-197.

O’Driscoll, SW. (1999) ‘Elbow instability’. *Acta Orthopaedica* 65 (4), pp.404-415.

Orthofix (2019) ‘Operative technique galaxy system upper limb’ [online], Italy: Orthofix Srl. Available at <http://abs.orthofix.it/db/resources/GF-1101-OPT-E0.pdf> [Accessed: 23 July 2019]

Ouyang, Y., Liao, Y., Liu, Z. and Fan, C. (2013) ‘Hinged external fixator and open surgery for severe elbow stiffness with distal humeral non-union’. *Orthopaedics* 36 (2), pp.186-192.

Ozel, O. and Demircay, E. (2016) ‘Review of management of unstable elbow fractures’. *World Journal of Orthopaedics* 7 (1), pp.50-54.

Panchal, S. and Murthi, A.M. (2012) ‘External fixators for the management of elbow stability’, *Shoulder and Elbow Trauma*. Available at: https://books.google.co.in/books?id=uoIZKQF0G50C&pg=PA223&lpg=PA223&dq=advantage%2Bof% [Accessed: 6 October 2017]

Pierrart, J., Bégué, T. and Mansat, P. (2015) ‘Terrible triad of the elbow: treatment protocol and outcome in a series of eighteen cases’. *Injury International Journal* 46, pp.8-12.

Poglia, P., Wehrli, L., Steinmetz, S. and Zermatten, P. (2016), ‘Radial nerve palsy after the use of an adjuvant hinged external fixator in a complex fracture-dislocation of the elbow: a case report and review of the literature’. *Journal of Medical Case Reports* [online] 10, pp.1-6. Available at <https://doi.org/10.1186/s13256-016-0904-9> [Accessed 25 August 2019]

Potini, VC., Ogunro, S., Henry, PDG., Ahmed, I. and Tan, V. (2015) ‘Complications associated with hinged external fixation for chronic elbow dislocations’. *Journal of Hand Surgery* 40, pp.730-737.

Ring, D., Jupiter, J. and Zilberfarb, J. (2002) ‘Posterior dislocation of the elbow with fractures of the radial head and coronoid’. *Journal of Bone and Joint Surgery—American* 84 (4), pp.547-551.

Ring, D., Bruinsma, WE. and Jupiter, JB. (2014) ‘Complications of hinged external fixation compared with cross-pinning of the elbow for acute and sub-acute instability’. *Clinical Orthopaedics and Related Research* 472 (7), pp.2044-2048.

Safoury, YA. and Atteya, MR. (2011) ‘Treatment of post-infection non-union of the supracondylar humerus with Ilizarov external fixator’. *Journal of Shoulder and Elbow Surgery* 20 (6), pp.873-879.

Saha, PK., Ray, S. and Behara, S. (2016) ‘Management of comminuted distal humerus fracture by minimal internal fixation and external fixation in the form of Joshi’s external stabilisation system in older individual: A prospective study’. *International Journal of Scientific Study* 4 (2), pp.34-39.

Sakai K., Shirahama M., Shiba N., Yoshida K. and Yoshida S. (2016) ‘Primary hinged external fixation of terrible triad injuries and olecranon fracture-dislocations of the elbow’. *Kurume Medical Journal* 63, pp.7-14.

Saunders, M., Lewis, P. and Thornhill, A. (2012) *Research methods for business students*. 6 edn. New York: Pearson Education Limited.

Schep, NW., De Haan, J., Iordens, GI., Tuinebreijer, WE., Bronkhorst, MW., Vries, MR., Goslings, JC., Ham, SJ., Rhemrev, S., Roukema GR., Schipper IB., Sintenie, JB., Meulen, HG., Thiel, TP., Vugt, AB., Verleisdonk, EJ., Vroemen, JP., Wittich, P., Patka, P., Lieshout, EM. and Hartog DD. (2011) 'A hinged external fixator for complex elbow dislocations: A multicentre prospective cohort study'. *Biomedical Central Musculoskeletal Disorders* [online] 12, pp.1-6. Available at <http://www.biomedcentral.com/1471-2474/12/130> [Accessed 24 August 2019]

Schippinger, G., Seibert, FJ., Steinbock, J. and Kucharczyk, M. (1999) 'Management of simple elbow dislocations. Does the period of immobilisation affect the eventual results?'. *Langenbeck's Archives of Surgery* 384 (3), pp.294-297.

Singh, AK. and Kumar, L., (2017), 'Role of external fixators in intertrochanteric femur fracture as definitive treatment in patients with comorbidities'. *Annals of International Medical and Dental Research* 3 (3), pp.18-22.

Smith and Nephew. (2011) *Ilizarov external fixator* [online], Cordova: Smith-Nephew Inc. Available at <http://www.smith-nephew.com/global/surgicaltechniques/trauma/ilizarov_tsf__hardware_reference_guide_71080244.pdf> [Accessed: 23 July 2019]

Taylor, F., Sims, M., Theis, JC. and Herbison, GP. (2012) 'Interventions for treating acute elbow dislocations in adults'. *Cochrane Database of Systematic Reviews* [online] (4). Available at <https://doi.org/10.1002/14651858.CD007908.pub2> [Accessed 24 August 2019]

Trimble, JE. and Fisher, C. (2006). *Handbook of ethical and responsible research with ethno-cultural populations and communities*. California: Sage Publications.

Wang, W., Jiang, S., Liu, S., Ruan, H. and Fan C. (2014) 'Stability of severely stiff elbows after complete open release: treatment by ligament repair with suture anchors and hinged external fixator'. *Journal of Shoulder and Elbow Surgery* 23, pp.1537-1544.

Wells, J. and Ablove, RH. (2008) 'Coronoid fractures of the elbow'. *Clinical Medicine and Research* [online] 6, (1) pp.40-44. Available at <https://doi.org/10.3121/cmr.2008.753> [Accessed 26 August 2019]

Yu, S., Wang, W., Liu, S., Ruan, H., Liu, J., Li, X., Zan, Y. and Fan, C. (2015) 'Arthrolysis and delayed internal fixation combined with hinged external fixation for elbow stiffness associated with mal-union or non-union of capitulum fracture'. *Journal of Shoulder and Elbow Surgery* 24, pp.941-946.

Zilkens, C., Graf, M., Anastasiadis, A., Smajic, S., Muhr, G. and Kälicke, T. (2009) 'Treatment of acute and chronic elbow instability with a hinged external fixator after fracture dislocation'. *Acta Orthopaedica* 75 (2), pp.167-174.